# BASEC Annual Report 2016

Descriptive statistics on research covered by the
Swiss Federal Act on Research involving Human Beings

January 1, 2016 – December 31, 2016

Schweizerische Eidgenossenschaft
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**Bundesamt für Gesundheit BAG**

swissethics

Schweizerische Ethikkommissionen für die Forschung am Menschen
Commissions d'éthique suisses relative à la recherche sur l'être humain
Commissioni etiche svizzere per la ricerca sull'essere umano
Swiss Ethics Committees on research involving humans

Report prepared by:
Clinical Trial Unit Basel
Department of Clinical Research
University Hospital Basel

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## List of abbreviations

| | |
|---|---|
| **BASEC** | Business Administration System for Ethics Committees |
| **AS1** | Analysis set 1: all projects submitted in the year 2016 |
| **AS2** | Analysis set 2: all projects approved in the year 2016 |
| **HRA** | Federal Act on Research involving Human Beings (Human Research Act) |
| **HRO** | Ordinance on Human Research with the Exception of Clinical Trials (Human Research Ordinance) |
| **ClinO** | Ordinance on Clinical Trials in Human Research (Clinical Trials Ordinance) |
| **IQR** | Inter-quartile range |
| **FOPH** | Federal Office of Public Health |
| **EC** | Ethics committee |
| **CCER** | Commission cantonale d'éthique de la recherche (Genève) |
| **CE-TI** | Comitato etico cantonale Ticino |
| **CER-VD** | Commission cantonale d'éthique de la recherche sur l'être humain Vaud |
| **EKNZ** | Ethikkommission Nordwest- und Zentralschweiz |
| **EKOS** | Ethikkommission Ostschweiz |
| **KEK-BE** | Kantonale Ethikkommission Bern |
| **KEK-ZH** | Kantonale Ethikkommission Zürich |

# 1 Introduction

The aim of this report is to describe research covered by the Swiss Federal Act on Research involving Human Beings (HRA). For this, data collected using the Business Administration System for Ethics Committees (BASEC) web portal maintained by the Swiss Ethics Committees on research involving humans (swissethics) were analysed. The initially provided report shall be updated on a yearly basis for the time period 2018–2020 and be extended by analyses exploring potential time trends.

The purpose of the BASEC web portal is to optimise the application process by providing a unique entry point for applications in the scope of the HRA irrespective of the involved ethics committees (ECs). Since the beginning of 2016, all applications are submitted via BASEC. The standardised and structured information on all submitted research projects provides a unique opportunity for a comprehensive overview on the Swiss human research landscape.

## 1.1 Report structure

In the subsequent section, the sources of the analysed data are described and limitations are discussed. This results in the definition of two analysis sets (AS): one based on submissions *(AS1)* and the other based on approved projects in the reporting year *(AS2)*. The analysis sets are described in detail in section 1.3.

First, an overview on the BASEC data in the true calendar year 2016 is provided by specifying input (submissions in the index years and pending decisions from previous year(s)) and output (decisions, pending decisions and withdrawals) in detail (chapter 2).

Second, chapter 3 describes all submissions *(AS1)* via the web portal in year 2016. A stratification by EC, project status and type of research gives insights into the workload of the individual ECs and the type of the submitted projects.

Third, chapter 4 provides a more scientific view on the projects with a descriptive analysis of various characteristics of all projects approved in 2016 based on the analysis set *AS2*.

Fourth, a more detailed view on the application process is provided in chapter 5. This analysis is mainly based on data provided by the individual ECs and gives insights into response times and the review process.

Some distinctive features in the implementation of the BASEC web form complicated the analysis of the data. These issues are briefly described in a separate document ("Addendum to the BASEC Report") together with a comment on the general design of BASEC and the interplay of its data with data on response times reported by the individual ECs.

## 1.2 Data source and limitations

This report is based on data entered into the BASEC web portal by two different parties:

1. All data concerning the submitted research projects are entered by the applicant.
2. With the exception of the submission date, all data on response times and on the review process are entered by the individual ethics committees under the supervision of swissethics.

A BASEC data export provided by swissethics dated April 2, 2018 has been used for this report.

### 1.2.1 Data provided by the applicant

The BASEC web portal enables the applicant to submit all information and documents needed by the ECs to assess the projects according to the HRA and its ordinances. The web interface is dynamic by showing/hiding fields depending on the type of research projects (e.g. clinical trial or 'further use' project) or depending on previous answers.

Within BASEC, the classification in different types of research projects is generally in conformity with the HRA and its ordinances. However, some compromises have been made with the aim of facilitating the application process. This includes projects that cover two groups of research projects defined by the law but constitute a single research project (e.g. clinical trial including further use of existing data; see section 1.3.3).

The HRA and its ordinances form the basis of the work of the ECs. Generally, the terminology and categories used in BASEC tend to be in close conformity with the law whenever there are legal restrictions relevant for the application process. Some questions and categories in the web portal are, however, BASEC-specific with the aim to further characterise the research projects.

It has to be kept in mind that the BASEC data have limitations: the data in BASEC are primarily entered and reviewed with the purpose of submitting/assessing a project application and not in view of a further scientific analysis. The data are entered solely by the applicant and not edited by the ECs directly after the submission. This means that information retrieved from BASEC, especially from submitted but not yet reviewed projects, may contain irregularities. The ECs review the content of an application primarily with respect to legal, regulatory and ethical compliance but not for logical inconsistencies that arise from the application process itself. Still, the ECs actively ask the project applicant to correct the data entered in BASEC if this is found to be obviously incorrect.

It may be discussed whether the individual responsibilities of applicants and ECs are clear and well defined enough and whether, for example, a catalogue of standard consistency checks may need to be defined. Many rule-based checks are already implemented within the dynamic BASEC interface. The detailed stratification of the data presented in this report may uncover logically impossible combinations of project characteristics which arise, e.g. due to imprecise formulations. These may lead to the implementation of additional rules and thereby improve data quality. Some issues observed during the analysis are described in the addendum of this report.

### 1.2.2 Data on response times and on the review process provided by individual ethics committees

For each project, the dates of specific milestones indicated in the ordinances (Art. 26 and 27 ClinO, Art. 16 and 17 HRO) are captured. The milestones are:

**Reception date:** The date when the applicant submits the project for the first time.

**First reaction date:** The date when the ethics committee notifies the project applicant of either the acceptance of the application (in this case the first reaction date coincides with the "date the application data declared complete"), or of any formal deficiency in the application documents and the need for resubmission.

**Date the application data declared complete:** The date at which the application data are considered formally complete and ready for review by ordinary, simplified or presidential procedure.

**First decision date:** Date of the decision after the first review procedure. The first decision date coincides with the "final decision date" if the project is approved (i.e. without charges) in the first run.

**Final decision date:** Date of the final decision which can be: approved (and all charges have been fulfilled), declined, non-consideration, withdrawn.

These dates are used to calculate response times which are presented in chapter 5 on pages 57ff. In addition to the dates, the ECs report for each project the outcome of the first and the final decision as well as the review procedure applied (ordinary, simplified, presidential). An overview of the different EC decisions can be found in Table 3 on page 14 with short descriptions as table footnotes.

Only the reception date is recorded automatically by the system. All other dates are entered in BASEC manually by the ECs. The completeness and consistency of these data are checked periodically by swissethics (irrespective of this report) and ECs are reminded when mandatory fields are found empty or when discrepancies are identified.

### 1.2.3 Post-processing of the BASEC data export

BASEC stores data submitted over the web form in key/value stores. A new version of the data for an application is generated whenever the submission button is clicked. The complete key/value data of all versions are available in coded form as a JSON dump via an API and data of the current project versions are available in tabular form. Both data sets have been made available by swissethics.

Generally, BASEC seems to perform data integrity checks essentially at the front-end level (the submission form) and not at the back-end, e.g. by defining and applying a data model. The detailed and machine-readable code books describing all the questions (data type, label, dependency rules hiding fields) and answers (for single and multiple choice fields) are provided by swissethics and are available as separate documents (`Fields.xlsx, answers.xlsx`).

swissethics performs some initial post-processing of the BASEC data export e.g. by parsing the JSON-data, checking the character encoding of the data, removing white spaces from numeric fields or by identifying potential damaged project versions.

Before starting the analysis, the data were subjected to additional integrity checks and post-processing. The following basic steps were performed specifically to prepare the data provided by swissethics for the analyses in this report:

- Load and parse the code books.
- Load the parsed JSON data provided by swissethics and extract the most recent version of each project.
- Decode the data by translating codes to the respective question and answer names using the code books.
- Reshape the decoded JSON data into tabular form.
- Check whether variable names agree with specifications in the "questions code book" and rename variable names if the names are ambiguous.
- Check whether the data type of each column is in accordance to the "answers code book" (inconsistencies are already communicated to swissethics and will be integrated in an updated version of the codebook), check if the levels of single and multiple choice answers agree with the specifications in the code book, and split multiple choice answers to multiple fields as needed.
- Apply the code book while loading the data.
- In a last step, a set of core variables used extensively in the report is processed for the purpose of standardising the answers (e.g. capitalising) and optimise them for presentation in tables (order levels, shorten long answers). In addition, some derived variables are built by combining several variables or grouping answers. These variables and other variables used for stratification are defined briefly at the beginning of the respective sections where they are used (see sections 4.3.1 and 4.4.1).

All data processing and analyses were done using the statistical software R version 3.5.1.

## 1.3 Analysis sets

### 1.3.1 Definition of analysis sets

**Definition:**

**AS1** The analysis set AS1 consists of all projects **submitted in 2016**. The AS1 includes all applications which have been submitted over the BASEC web portal irrespective of whether the projects were subsequently approved or not.

**AS2** The analysis set AS2 consists of all projects **approved in 2016** irrespective of whether the projects were submitted in the reporting year or before.

The BASEC data can be used to quantify and compare the workload of the individual ECs. This analysis is performed on the **entirety of all submissions in a given year**. We defined this as the **first analysis set *AS1***. For each project the most recent version of the submitted data (e.g. type of research, risk category) at the time of the data export is used. For a fraction of the projects, the approval status may be pending and the project characteristics may be subject to changes.

A BASEC data export always presents a snapshot. Some projects have already been assessed and a final decision has been made, and other projects are pending for various reasons: the application data are still incomplete, the decision by the EC is pending or the EC makes the decision on the project dependent on certain charges/conditions. Furthermore, submitted projects may later be declined by the EC, the project may not be covered by the HRA (non-consideration) or may be withdrawn by the applicant (including submissions that are never completed).

During the application process, the BASEC data are subject to change with the quality and completeness of the data increasing as the application process progresses. Even for approved projects the data may change over time due to amendments.

All these restrictions have an effect on the resulting analyses and their interpretation. A scientific analysis of the characteristics of the research projects can therefore only be performed on the subset of **approved projects in a given year** for which the data tend to be complete and reviewed to a certain extent by the ECs. We defined this as the **second analysis set *AS2***. The set of approved projects as opposed to declined and withdrawn/non-considered projects represents research that is actually going to be conducted and thereby provides insights on the current medical research landscape.

In addition to the above described limitations with regard to the content of applications, the data are capped on both ends, which further complicates the comparison of the data over years (see Figure 1): only submissions after the beginning of 2016 are captured in BASEC, and, the data are censored at the time of data export.

### 1.3.2 Influence of time on project status

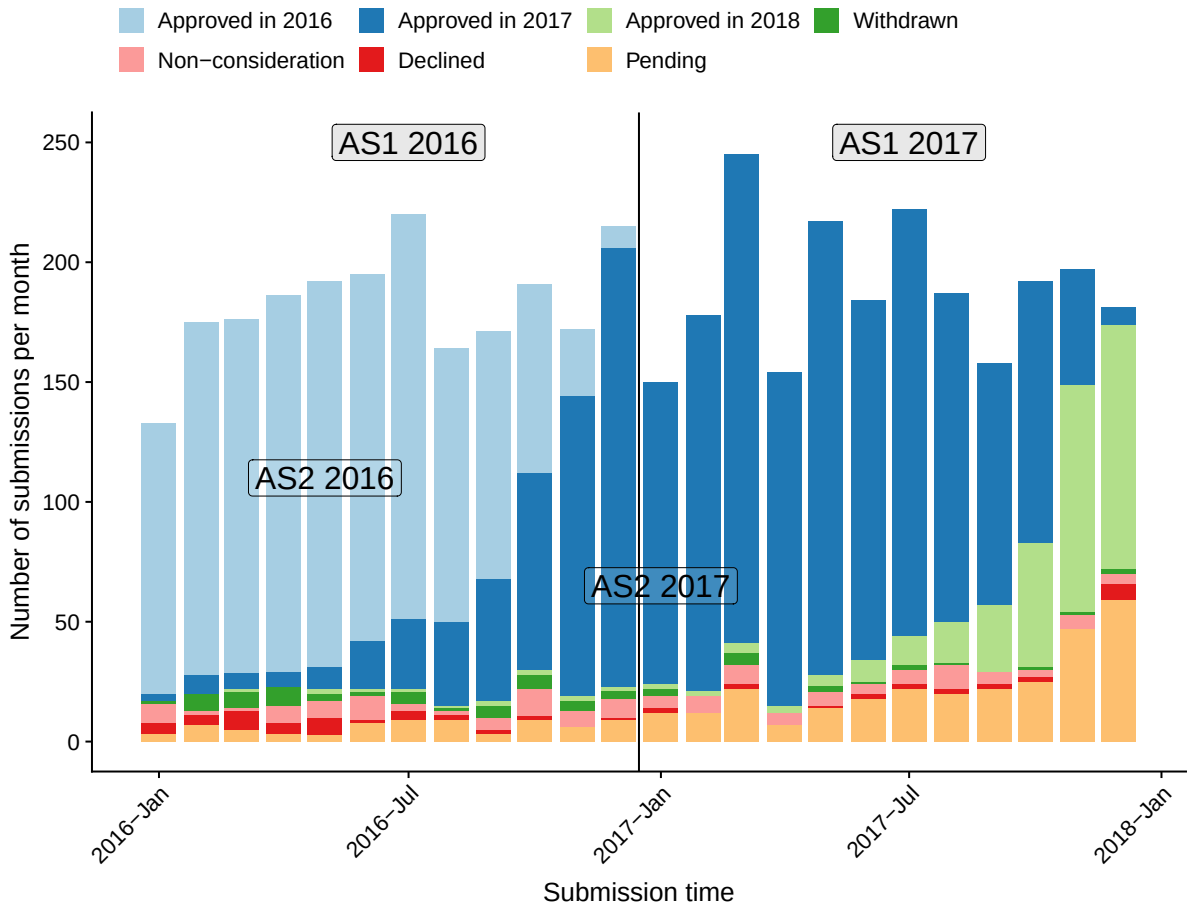


**Figure 1:** Overview of submissions via BASEC in the years 2016-2017 coloured by the current status as of the time of the data export (April 2, 2018).

Figure 1 shows all submissions via BASEC in the years 2016 and 2017. Each bar represents the number of submissions in a given month. The bars are coloured according to the current status of the respective submissions as of the time of the data export.

The proportion of projects not approved (declined, withdrawn, non-consideration) is quite stable over time. These projects are not part of *AS2* and will not be analysed scientifically. The proportion of pending projects is low for 2016: projects that have been pending for a long time (after reminding the applicants for multiple times) are periodically reclassified by swissethics to withdrawn or declined, depending whether the project passed the 'application data declared complete' milestone. The proportion of pending projects increases over the course of the year 2017, since the data export point is identical for both years (April 2, 2018).

For approved projects, the year of the final decision is provided. When focusing on projects approved in a given year *(AS2)*, the 2016 data set only includes projects submitted in 2016 (after the introduction of BASEC; in light blue). In contrast to this, the 2017 data set also includes submissions from 2016 (dark blue portion on the left side). The fact that the 2016 AS2 data set is truncated on the left side makes a longitudinal analysis of the 2016 and 2017 AS2 data meaningless. However, in the future, when

comparing 2017 to 2018 and subsequent years, the AS2 data will not suffer from left-truncation anymore, and therefore will allow a meaningful longitudinal analysis.

The two analysis sets represent compromises and are a trade-off between how exhaustive the data set is and the quality/completeness of the individual data points, i.e. the projects. The analysis set *AS1* focuses on the former aspect and *AS2* on the latter.

### 1.3.3 Definition of the basic unit of analysis

For both analysis sets, individual BASEC submissions form the basis of this report, irrespective of whether a single EC or multiple ECs are involved in the assessment. Projects involving multiple ECs were counted only once and are assigned to the lead EC. [1]

Throughout this report, mono-centric and multi-centric studies are defined based on the number of involved study sites but irrespective of the number of involved ECs (see the definition of the main stratification variables in chapter 4.3.1).

Projects with characteristics that simultaneously fall into two separate legally defined project types represent a special case. In BASEC, such projects are called "combined research projects" and consist of the following two types:

1. Research involving a combination of a clinical trial (ClinO) or a research project involving persons (HRO Chapter 2) and the further-use of existing data or biological material (HRO Chapter 3). BASEC allows these combined projects to be submitted as a single research project.
2. Research involving a combination of a medicinal product and a medical device such as drug-eluting stents.

Stratification of such projects by project type is not straightforward. In the overarching analyses, we count combined research projects only once like single research projects. However, when looking at subgroups of projects (e.g. 'further use' projects) we count them separately in each category since in this case the specific characteristics of these projects are in focus. For instance, clinical trials or research with persons according to the HRO combined with 'further use' are considered a single research project and are attributed to the category ClinO or research with persons (HRO) in all overview tables (Tables 2, 5 and 8ff). However, in the subgroup analysis of 'further use' projects, these combined projects are included. Explanatory footnotes are added to the relevant tables. Similarly, medical device/medicinal product combinations are counted once in the overview tables and are analysed separately in the subgroup analysis.

[1] Exception: In section 3.2 on page 17, the data are summarised from a EC perspective by counting individual evaluations thereby assigning projects involving multiple local committees to all ECs.

## 2 BASEC data in the calendar year 2016

**Table 1:** Calendar-year-centric view on the BASEC data. Note that pending applications of projects submitted before 2016 are not stored in BASEC.

| | | | n | % |
|---|---|---|---|---|
| Input | | Submission in 2016 (AS1) | 2180 | 100.0 |
| | | Project with pending first decision from the previous year | 0 | 0.0 |
| | | Grand Total Input 2016 | 2180 | 100.0 |
| Output | Final decision in 2016 | Approvals (AS2) | 1381 | 63.3 |
| | | Rejections (declined projects) | 34 | 1.6 |
| | | Non-considerations | 65 | 3.0 |
| | | Total Decisions | 1480 | 67.9 |
| | Withdrawn during 2016 | Withdrawal before first decision | 14 | 0.6 |
| | | Withdrawal after first decision 'approvals with charges' | 3 | 0.1 |
| | | Withdrawal after first decision 'not-yet-approved projects with conditions' | 29 | 1.3 |
| | | Total Withdrawn | 46 | 2.1 |
| | Pending at end of 2016 | *Pending first decision* | *249* | *11.4* |
| | | *Pending final decision (first decision issued)* | *405* | *18.6* |
| | | Total Pending | 654 | 30.0 |
| | | Grand Total Output 2016 | 2180 | 100.0 |

Discrepancies in the number of decisions presented here and in subsequent tables are explained by the different cut-off dates: here only decisions in calendar year are considered whereas in tables based on the AS1 all decisions until the date of data export are taken into account.

# 3 Overview of all projects submitted to BASEC in 2016 (AS1)

**Table 2:** Total number of research projects **submitted via BASEC in 2016** (analysis set AS1), including information on type of research and the legal basis.

| Type of research | Legal basis | n | $\%_{col}$ |
|---|---|---|---|
| Clinical trial | ClinO | 574 [1] | 26.3 |
| Research involving persons, but not a clinical trial | HRO, Chapter 2 | 757 [2] | 34.7 |
| Further use of health-related personal data and/or biological material | HRO, Chapter 3 | 827 | 37.9 |
| Research involving deceased persons | HRO, Chapter 4 | 20 | 0.9 |
| Research involving embryos and fetuses from induced abortions or stillbirths | HRO, Chapter 5 | 2 | 0.1 |
| Total number | | 2180 | 100.0 |

[1] 5 of these projects also include an application for further use of data/biological material.
[2] 2 of these projects also include an application for further use of data/biological material.

**Description of distinctive features of the results:**

Only about 12% of the submitted projects are already approved at the first review process (i.e. first decision). For the majority of applications a potential future approval is bound to conditions. Compared to conditions, a study with decision 'approved with charges' is considered approved, and the fulfilment of the charges is a presidential decision in addition (personal communication by swissethics). However, there is also a scope of discretion between conditions and charges. This may explain to some extent the differences found between individual ECs in Table 4 on the next page.

**Table 3:** Status information of all projects submitted in 2016. This information is manually curated by the individual ethics committees.

| | | n | $\%_{col}$ |
|---|---|---|---|
| First decision | Approved [1] | 239 | 11.0 |
| | Approved with charges [2] | 626 | 28.7 |
| | Not approved, conditions [3] | 1166 | 53.5 |
| | Declined | 38 | 1.7 |
| | Non-consideration [4] | 73 | 3.3 |
| | Pending first decision [5] | 38 | 1.7 |
| Final decision | Approved [6] | 1943 | 89.1 |
| | Declined | 41 | 1.9 |
| | Non-consideration | 71 | 3.3 |
| | Withdrawn | 53 | 2.4 |
| | Pending final decision [7] | 72 | 3.3 |
| Review procedure | Ordinary [8] | 406 | 18.6 |
| | Simplified [9] | 1507 | 69.1 |
| | Presidential [10] | 229 | 10.5 |
| | Pending first decision | 38 | 1.7 |
| | Total number in AS1 | 2180 | 100.0 |

[1] Projects already approved in the first review process.
[2] Charges: The projects are approved but with charges.
[3] Conditions: These projects are not approved until the conditions are addressed.
[4] Non-consideration: Research not covered by the HRA.
[5] Information missing: The status information was missing at the time of the report generation.
[6] Note that this includes projects approved both in the index year as well as in the subsequent year(s) until the time of the data export which explains the different numbers in Tables 3 and 9.
[7] Pending at export date. 33.3% of the pending projects were submitted in the last quarter of the reporting year.
[8] Decision taken at full commission meeting by at least seven members of the ethics committee, as per the provisions of Art. 5, OrgO-HRA.
[9] Decision taken by three members of the ethics committee, as per the provisions of Art. 6 OrgO-HRA.
[10] Decision taken by the president or vice-president of the ethics committee, as per the provisions of Art. 7 OrgO-HRA.

## 3.1 Submissions per ethics committee

**Table 4:** Overview of application details of all projects **submitted** via BASEC in 2016 (analysis set AS1) by ethics committee (for abbreviations see page 4).

| | | | | Ethics committee | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Total | | KEK-ZH | | EKNZ | | CER-VD | | KEK-BE | | CCER | | EKOS | | CE-TI | |
| | | N | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ |
| First decision | Approved | 239 | 11.0 | 55 | 9.2 | 61 | 14.0 | 34 | 8.6 | 33 | 9.9 | 14 | 5.5 | 25 | 29.1 | 17 | 23.3 |
| | Approved with charges [1] | 626 | 28.7 | 41 | 6.8 | 290 | 66.4 | 180 | 45.3 | 27 | 8.1 | 35 | 13.7 | 37 | 43.0 | 16 | 21.9 |
| | Not approved, conditions [2] | 1166 | 53.5 | 445 | 74.2 | 78 | 17.8 | 164 | 41.3 | 246 | 74.1 | 178 | 69.8 | 19 | 22.1 | 36 | 49.3 |
| | Declined | 38 | 1.7 | 13 | 2.2 | 1 | 0.2 | 5 | 1.3 | 2 | 0.6 | 15 | 5.9 | 1 | 1.2 | 1 | 1.4 |
| | Non-consideration [3] | 73 | 3.3 | 31 | 5.2 | 1 | 0.2 | 12 | 3.0 | 18 | 5.4 | 8 | 3.1 | 2 | 2.3 | 1 | 1.4 |
| | Pending first decision | 38 | 1.7 | 15 | 2.5 | 6 | 1.4 | 2 | 0.5 | 6 | 1.8 | 5 | 2.0 | 2 | 2.3 | 2 | 2.7 |
| Final decision | Approved | 1943 | 89.1 | 527 | 87.8 | 423 | 96.8 | 355 | 89.4 | 288 | 86.7 | 207 | 81.2 | 79 | 91.9 | 64 | 87.7 |
| | Declined | 41 | 1.9 | 13 | 2.2 | 1 | 0.2 | 5 | 1.3 | 5 | 1.5 | 16 | 6.3 | 1 | 1.2 | | |
| | Non-consideration | 71 | 3.3 | 29 | 4.8 | 1 | 0.2 | 13 | 3.3 | 18 | 5.4 | 9 | 3.5 | | | 1 | 1.4 |
| | Withdrawn | 53 | 2.4 | 11 | 1.8 | 8 | 1.8 | 8 | 2.0 | 13 | 3.9 | 8 | 3.1 | | | 5 | 6.8 |
| | Pending final decision | 72 | 3.3 | 20 | 3.3 | 4 | 0.9 | 16 | 4.0 | 8 | 2.4 | 15 | 5.9 | 6 | 7.0 | 3 | 4.1 |
| Review procedure | Ordinary | 406 | 18.6 | 92 | 15.3 | 82 | 18.8 | 54 | 13.6 | 68 | 20.5 | 25 | 9.8 | 15 | 17.4 | 70 [4] | 95.9 |
| | Simplified | 1507 | 69.1 | 381 | 63.5 | 312 | 71.4 | 304 | 76.6 | 240 | 72.3 | 213 | 83.5 | 57 | 66.3 | | |
| | Presidential | 229 | 10.5 | 112 | 18.7 | 37 | 8.5 | 37 | 9.3 | 18 | 5.4 | 12 | 4.7 | 12 | 14.0 | 1 | 1.4 |
| | Pending first decision | 38 | 1.7 | 15 | 2.5 | 6 | 1.4 | 2 | 0.5 | 6 | 1.8 | 5 | 2.0 | 2 | 2.3 | 2 | 2.7 |
| | Total number in AS1 | 2180 | 100.0 | 600 | 100.0 | 437 | 100.0 | 397 | 100.0 | 332 | 100.0 | 255 | 100.0 | 86 | 100.0 | 73 | 100.0 |

[1] Charges: The projects are approved but with charges.
[2] Conditions: These projects are not approved until the conditions are addressed.
[3] Non-consideration: Research not covered by the HRA.
[4] CE-TI reviews all projects in an 'Ordinary procedure'.

**Table 5:** Number of **submissions in 2016** (analysis set AS1) by type of research project and ethics committee. Projects involving multiple ECs are assigned to the lead EC.

| | | | | | Ethics committee | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | KEK-ZH | | EKNZ | | CER-VD | | KEK-BE | | CCER | | EKOS | | CE-TI | |
| **Type of research** | **Research details** | **Risk cat.** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** |
| Clinical trial | Medicinal products | A | 23 | 10.1 | 2 | 3.7 | 3 | 5.1 | 4 | 15.4 | 5 | 12.5 | 5 | 33.3 | 4 | 25.0 | | |
| | | B | 61 | 26.8 | 13 | 24.1 | 20 | 33.9 | 6 | 23.1 | 12 | 30.0 | 5 | 33.3 | 1 | 6.2 | 4 | 22.2 |
| | | C | 144 | 63.2 | 39 | 72.2 | 36 | 61.0 | 16 | 61.5 | 23 | 57.5 | 5 | 33.3 | 11 | 68.8 | 14 | 77.8 |
| | | All | 228 | 100.0 | 54 | 100.0 | 59 | 100.0 | 26 | 100.0 | 40 | 100.0 | 15 | 100.0 | 16 | 100.0 | 18 | 100.0 |
| | Medical devices | A | 105 | 73.9 | 36 | 72.0 | 15 | 75.0 | 8 | 80.0 | 21 | 63.6 | 14 | 82.4 | 6 | 85.7 | 5 | 100.0 |
| | | C | 37 | 26.1 | 14 | 28.0 | 5 | 25.0 | 2 | 20.0 | 12 | 36.4 | 3 | 17.6 | 1 | 14.3 | | |
| | | All | 142 | 100.0 | 50 | 100.0 | 20 | 100.0 | 10 | 100.0 | 33 | 100.0 | 17 | 100.0 | 7 | 100.0 | 5 | 100.0 |
| | Other clinical trials | A | 169 | 88.9 | 46 | 88.5 | 38 | 90.5 | 21 | 91.3 | 19 | 79.2 | 26 | 92.9 | 10 | 90.9 | 9 | 90.0 |
| | | B | 21 | 11.1 | 6 | 11.5 | 4 | 9.5 | 2 | 8.7 | 5 | 20.8 | 2 | 7.1 | 1 | 9.1 | 1 | 10.0 |
| | | All | 190 | 100.0 | 52 | 100.0 | 42 | 100.0 | 23 | 100.0 | 24 | 100.0 | 28 | 100.0 | 11 | 100.0 | 10 | 100.0 |
| | Combination drugs/devices | A | 3 | 50.0 | 1 | 33.3 | | | | | 2 | 100.0 | | | | | | |
| | | C | 3 | 50.0 | 2 | 66.7 | | | | | | | 1 | 100.0 | | | | |
| | | All | 6 | 100.0 | 3 | 100.0 | | | | | 2 | 100.0 | 1 | 100.0 | | | | |
| | Transplant products | C | 7 | 100.0 | 2 | 100.0 | | | 3 | 100.0 | | | 1 | 100.0 | | | 1 | 100.0 |
| | | All | 7 | 100.0 | 2 | 100.0 | | | 3 | 100.0 | | | 1 | 100.0 | | | 1 | 100.0 |
| | Gene therapy | C | 1 | 100.0 | | | | | | | 1 | 100.0 | | | | | | |
| | | All | 1 | 100.0 | | | | | | | 1 | 100.0 | | | | | | |
| | All | All | 574 | 100.0 | 161 | 100.0 | 121 | 100.0 | 62 | 100.0 | 100 | 100.0 | 62 | 100.0 | 34 | 100.0 | 34 | 100.0 |
| Research w/ persons | | A | 732 | 96.7 | 157 | 95.2 | 141 | 96.6 | 172 | 97.2 | 105 | 98.1 | 106 | 95.5 | 29 | 100.0 | 22 | 100.0 |
| | | B | 25 | 3.3 | 8 | 4.8 | 5 | 3.4 | 5 | 2.8 | 2 | 1.9 | 5 | 4.5 | | | | |
| | | All | 757 | 100.0 | 165 | 100.0 | 146 | 100.0 | 177 | 100.0 | 107 | 100.0 | 111 | 100.0 | 29 | 100.0 | 22 | 100.0 |
| Further use | | n.a. | 827 | 100.0 | 270 | 100.0 | 163 | 100.0 | 156 | 100.0 | 124 | 100.0 | 74 | 100.0 | 23 | 100.0 | 17 | 100.0 |
| Deceased, embryos | | n.a. | 22 | 100.0 | 4 | 100.0 | 7 | 100.0 | 2 | 100.0 | 1 | 100.0 | 8 | 100.0 | | | | |
| Total number | | | 2180 | 100.0 | 600 | 100.0 | 437 | 100.0 | 397 | 100.0 | 332 | 100.0 | 255 | 100.0 | 86 | 100.0 | 73 | 100.0 |

Note that this table includes all BASEC submissions irrespective of whether the project was approved. The type of project and the risk category at the time of the data export is used.

## 3.2 Individual evaluations by lead or local ethics committees

**Table 6:** Perspective of the ethics committee (EC): Number of applications to be evaluated (analysis set AS1). Note that this table includes only local ECs involved at submission or reported until the date of data export.

| | n | % |
|---|---|---|
| Single EC involved | 1874 | 65.8 |
| Multiple ECs involved: lead EC | 306 | 10.8 |
| Multiple ECs involved: local EC | 666 | 23.4 |
| Total submissions to be evaluated | 2846 | 100.0 |

**Table 7:** Perspective of the ethics committee (EC): Number of submissions to be evaluated per EC.

| | Ethics committee | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | KEK-ZH | | EKNZ | | KEK-BE | | CER-VD | | CCER | | EKOS | | CE-TI | |
| | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ |
| Single EC involved | 532 | 74.2 | 376 | 68.1 | 268 | 62.2 | 359 | 73.0 | 226 | 64.6 | 58 | 33.9 | 55 | 41.4 |
| Multiple: lead EC | 68 | 9.5 | 61 | 11.1 | 64 | 14.8 | 38 | 7.7 | 29 | 8.3 | 28 | 16.4 | 18 | 13.5 |
| Multiple: local EC | 117 | 16.3 | 115 | 20.8 | 99 | 23.0 | 95 | 19.3 | 95 | 27.1 | 85 | 49.7 | 60 | 45.1 |
| Total submissions | 717 | 100.0 | 552 | 100.0 | 431 | 100.0 | 492 | 100.0 | 350 | 100.0 | 171 | 100.0 | 133 | 100.0 |

# 4 Scientific characterisation of projects approved in 2016 (AS2)

## 4.1 Overview

**Table 8:** Total number of research projects **approved in 2016** (analysis set AS2) per type of research, including information on the legal basis.

| Type of research | Legal basis | n | $\%_{col}$ |
|---|---|---|---|
| Clinical trial | ClinO | 324 [1] | 23.5 |
| Research involving persons, but not a clinical trial | HRO, Chapter 2 | 473 [2] | 34.3 |
| Further use of health-related personal data and/or biological material | HRO, Chapter 3 | 566 | 41.0 |
| Research involving deceased persons | HRO, Chapter 4 | 17 | 1.2 |
| Research involving embryos and fetuses from induced abortions or stillbirths | HRO, Chapter 5 | 1 | 0.1 |
| Total number | | 1381 | 100.0 |

[1] 2 of these projects also include 'further use' of existing data and/or material.
[2] 0 of these projects also include 'further use' of existing data and/or material.

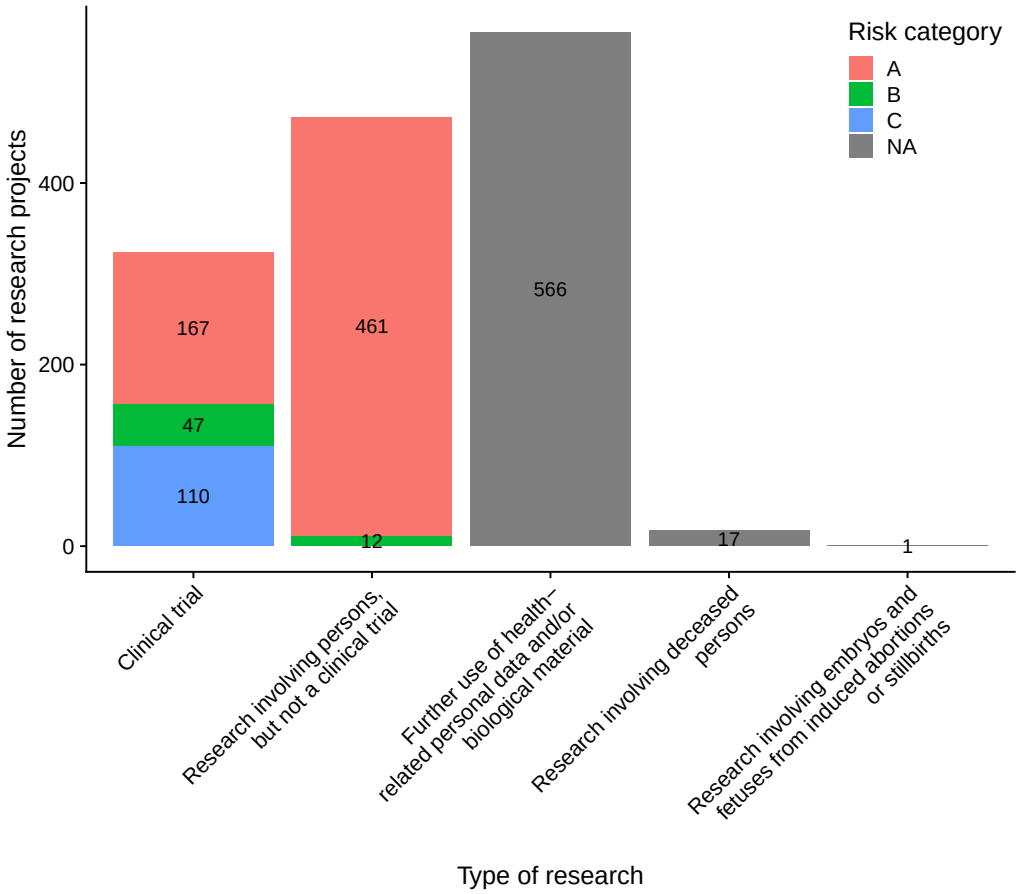


**Figure 2:** Stratification of all research projects by type of research and risk category.

## 4.2 Application process

**Table 9:** Overview of review procedure and first decision for all projects approved in 2016 (i.e. the final decision is 'approved'; AS2). A fraction of the projects are already approved at the 'first decision', the remaining at the 'final decision'. For a definition of all terms see Table 3 on page 14.

| | | n | $\%_{col}$ |
|---|---|---|---|
| Submission year | 2015 [1] | 0 | 0.0 |
| | 2016 | 1381 | 100.0 |
| Review procedure | Ordinary | 225 | 16.3 |
| | Simplified | 1033 | 74.8 |
| | Presidential | 123 | 8.9 |
| First decision | Approved | 222 | 16.1 |
| | Approved with charges | 488 | 35.3 |
| | Not approved, conditions | 667 | 48.3 |
| | Declined | 2 | 0.1 |
| | Non-consideration | 2 | 0.1 |
| | Total number in AS2 | 1381 | 100.0 |

[1] BASEC was introduced in 2016. In this initial report of the year 2016, the analysis set AS2 therefore contains only projects submitted and approved in 2016.

**Table 10:** Overview of application details for all projects approved in 2016 - per ethics committee.

| | | | | Ethics committee | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Total | | KEK-ZH | | EKNZ | | CER-VD | | KEK-BE | | CCER | | EKOS | | CE-TI | |
| | | N | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ | n | $\%_{col}$ |
| Submission year | 2015 | 0 | 0.0 | | | | | | | | | | | | | | |
| | 2016 | 1381 | 100.0 | 348 | 100.0 | 322 | 100.0 | 266 | 100.0 | 206 | 100.0 | 128 | 100.0 | 64 | 100.0 | 47 | 100.0 |
| First decision | Approved | 222 | 16.1 | 49 | 14.1 | 57 | 17.7 | 30 | 11.3 | 33 | 16.0 | 13 | 10.2 | 23 | 35.9 | 17 | 36.2 |
| | Approved with charges [1] | 488 | 35.3 | 32 | 9.2 | 221 | 68.6 | 145 | 54.5 | 25 | 12.1 | 26 | 20.3 | 27 | 42.2 | 12 | 25.5 |
| | Not approved, conditions [2] | 667 | 48.3 | 267 | 76.7 | 44 | 13.7 | 90 | 33.8 | 148 | 71.8 | 88 | 68.8 | 12 | 18.8 | 18 | 38.3 |
| | Declined | 2 | 0.1 | | | | | 1 | 0.4 | | | 1 | 0.8 | | | | |
| | Non-consideration [3] | 2 | 0.1 | | | | | | | | | | | 2 | 3.1 | | |
| Review procedure | Ordinary [4] | 225 | 16.3 | 40 | 11.5 | 60 | 18.6 | 34 | 12.8 | 26 | 12.6 | 7 | 5.5 | 11 | 17.2 | 47 | 100.0 |
| | Simplified | 1033 | 74.8 | 255 | 73.3 | 237 | 73.6 | 210 | 78.9 | 178 | 86.4 | 112 | 87.5 | 41 | 64.1 | | |
| | Presidential | 123 | 8.9 | 53 | 15.2 | 25 | 7.8 | 22 | 8.3 | 2 | 1.0 | 9 | 7.0 | 12 | 18.8 | | |
| | Total number in AS2 | 1381 | 100.0 | 348 | 100.0 | 322 | 100.0 | 266 | 100.0 | 206 | 100.0 | 128 | 100.0 | 64 | 100.0 | 47 | 100.0 |

[1] Charges: the projects are approved but with charges.
[2] Conditions: These projects are not approved until the conditions are addressed.
[3] Non-consideration: Research not covered by the HRA.
[4] CE-TI exclusively uses the ordinary procedure.

## 4.3 Stratification by project characteristics

In Tables 11-16 on page 24-31, the approved projects are grouped row-wise by type of research (the corresponding legal basis is denoted in the first table) and stratified column-wise by generic project characteristics (design, project initiator, etc.).

For the most important types of research projects, subgroup analyses are provided in the following sections. Links to the sub-chapter covering the corresponding subgroup analysis are embedded in Table 11. In the subgroup analyses starting on page 32, a similar table structure is used with more generic characteristics in the columns and subgroup specific characteristics in the rows.

### 4.3.1 Description and derivation of stratification variables

**Risk category:** The risk category is used as a stratification variable in all tables. In general, category "A" stands for low risk - however, the exact meaning depends on the type of research project and is defined in the respective ordinances (ClinO Art. 19, 20, 49, 61 and HRO Art. 7). The risk category is derived from the approved project's final risk category ruling stored in BASEC.

**Study design:** Mono-centric and multi-centric studies are defined based on the number of involved study sites irrespective of whether single or multiple ECs are involved. This is a variable derived from two BASEC questions: "How many research sites in Switzerland are involved in the project?" and "Is the project taking place in countries other than Switzerland?". Mono-centric studies have only one site in Switzerland and no sites in other countries.

**Initiator:** The initiator of the project is derived from the answer to the BASEC question "Who initiated the project? Indicate here who had the original idea for the research project (do not indicate here who is financing, conducting or leading the project)". Allowed answers are "Investigator", "Industry" and "Other" (very rare). To keep it simple, studies with an initiator defined as "Other" are considered investigator initiated studies in the tables. In Table 4.5.1 on page 55, the above classification is compared to the main financing source indicating that this question indeed seems to be a good proxy to distinguish industry from academic studies.

**Research to obtain a degree:** The question in BASEC is "Is this research project solely or principally designed to obtain a degree? (Master/PhD/etc)", with allowed answers "yes" or "no".

**Vulnerable persons:** This is a multiple choice field in BASEC and the allowed answers are: "None", "Embryos / fetuses intrauteri", "Children (0-13, until one day before 14th birthday)", "Adolescents (14-17, until one day before 18th birthday)", "Emergencies (transient incapacity to consent, HRA art 30-31, ClinO art 15-17, HRO art 11)", "Pregnant women", "prisoners", "Persons unable to consent (long-term incapacity to consent, HRA art 21-24)", "Healthy volunteers". To save table space, the 3 rarest categories are grouped to "Others". This question is not asked in BASEC for projects involving "Further use" or "Deceased persons".

**Ionising radiation:** The question in BASEC is "Does your study involve ionising radiation?". The allowed answers are: "No", "Yes, the main focus of the project is related to radiopharmaceuticals (medicinal products) or to devices emitting ionising radiation (medical devices)", "Yes, but the study is only using ionising radiation for imaging/control purposes". This question is shown only for clinical trials and research involving persons according to HRO chapter 2.

**Ethics committee:** Column-wise percentages are reported when stratifying by lead EC.

**Application procedure:** The information on the applied review procedure (ordinary, simplified, presidential) as well as the first decision is reported by the individual ECs.

### 4.3.2 Risk category, study design and initiator

**Table 11:** Stratification of approved projects by study design and initiator. Subgroups in blue refer to chapters with the respective subgroup analyses and the legal basis is denoted in parentheses.

| | | | | | Study design | | | | | | Initiator | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Mono | | Multi CH | | Multi Int. | | Industry | | Investigator | |
| Type of research | Research details | Risk cat. | N | %col | n | %row | n | %row | n | %row | n | %row | n | %row |
| Clinical trial (ClinO) | Medicinal products (ClinO Art 19) | A | 13 | 9.0 | 7 | 53.8 | 3 | 23.1 | 3 | 23.1 | 2 | 15.4 | 11 | 84.6 |
| | | B | 36 | 25.0 | 10 | 27.8 | 4 | 11.1 | 22 | 61.1 | 16 | 44.4 | 20 | 55.6 |
| | | C | 95 | 66.0 | 16 | 16.8 | 6 | 6.3 | 73 | 76.8 | 75 | 78.9 | 20 | 21.1 |
| | | All | 144 | 100.0 | 33 | 22.9 | 13 | 9.0 | 98 | 68.1 | 93 | 64.6 | 51 | 35.4 |
| | Medical devices (ClinO Art 20) | A | 50 | 79.4 | 33 | 66.0 | 2 | 4.0 | 15 | 30.0 | 15 | 30.0 | 35 | 70.0 |
| | | C | 13 | 20.6 | 6 | 46.2 | 1 | 7.7 | 6 | 46.2 | 6 | 46.2 | 7 | 53.8 |
| | | All | 63 | 100.0 | 39 | 61.9 | 3 | 4.8 | 21 | 33.3 | 21 | 33.3 | 42 | 66.7 |
| | Other clinical trials (ClinO Art 61) | A | 104 | 90.4 | 77 | 74.0 | 10 | 9.6 | 17 | 16.3 | 10 | 9.6 | 94 | 90.4 |
| | | B | 11 | 9.6 | 7 | 63.6 | 1 | 9.1 | 3 | 27.3 | | | 11 | 100.0 |
| | | All | 115 | 100.0 | 84 | 73.0 | 11 | 9.6 | 20 | 17.4 | 10 | 8.7 | 105 | 91.3 |
| | Combination drugs/devices | C | 1 | 100.0 | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | All | 1 | 100.0 | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | Transplant products (ClinO Art 21) | C | 1 | 100.0 | | | | | 1 | 100.0 | 1 | 100.0 | | |
| | | All | 1 | 100.0 | | | | | 1 | 100.0 | 1 | 100.0 | | |
| | Gene therapy (ClinO Art 22) | All | 0 | | | | | | | | | | | |
| | Transplantation (ClinO Art 49) | All | 0 | | | | | | | | | | | |
| | All | All | 324 | 100.0 | 157 | 48.5 | 27 | 8.3 | 140 | 43.2 | 125 | 38.6 | 199 | 61.4 |
| Research w/ persons (HRO Chapter 2) | | A | 461 | 97.5 | 343 | 74.4 | 36 | 7.8 | 82 | 17.8 | 39 | 8.5 | 422 | 91.5 |
| | | B | 12 | 2.5 | 8 | 66.7 | | | 4 | 33.3 | 1 | 8.3 | 11 | 91.7 |
| | | All | 473 | 100.0 | 351 | 74.2 | 36 | 7.6 | 86 | 18.2 | 40 | 8.5 | 433 | 91.5 |
| Further use (HRO Chapter 3) | | n.a. | 566 | 100.0 | 485 | 85.7 | 30 | 5.3 | 51 | 9.0 | 23 | 4.1 | 543 | 95.9 |
| Deceased, embryos (HRO Chapter 4+5) | | n.a. | 18 | 100.0 | 14 | 77.8 | 1 | 5.6 | 3 | 16.7 | 1 | 5.6 | 17 | 94.4 |
| Total number | | | 1381 | 100.0 | 1007 | 72.9 | 94 | 6.8 | 280 | 20.3 | 189 | 13.7 | 1192 | 86.3 |

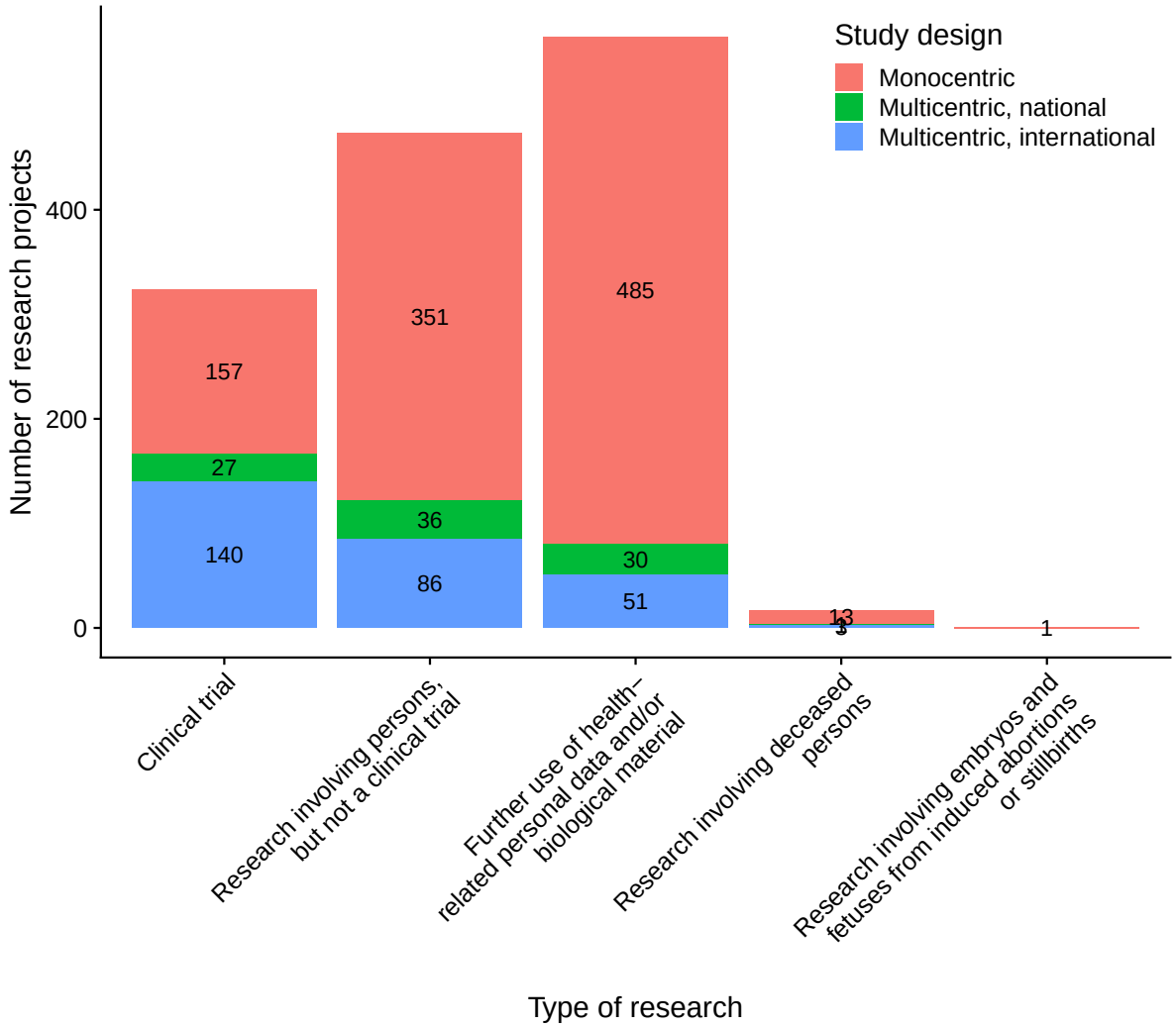


**Figure 3:** Stratification of all research projects by type of research and study design.

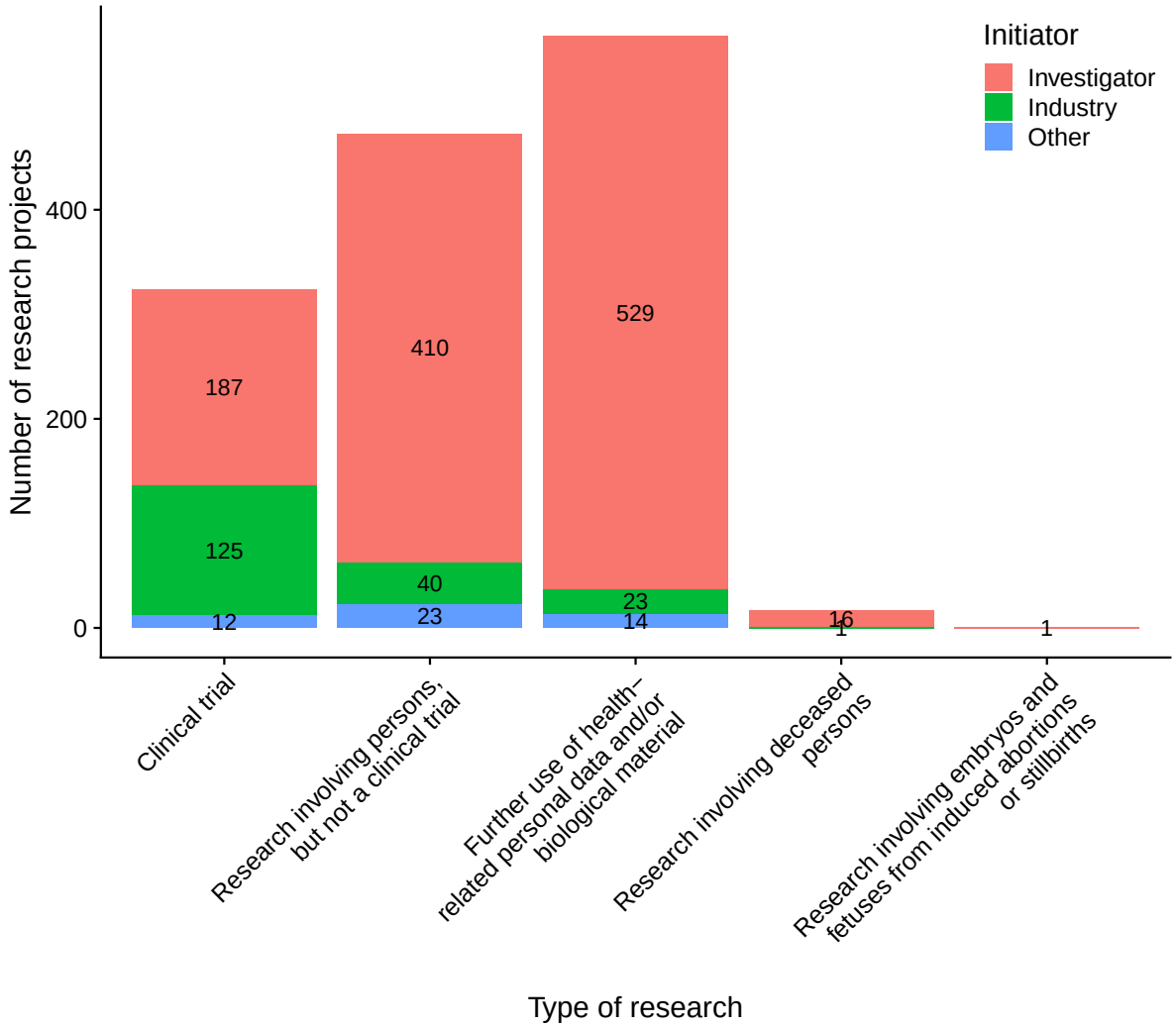


**Figure 4:** Stratification of all research projects by type of research and initiator.

### 4.3.3 Research to obtain degree

**Table 12:** Stratification of all approved projects by whether the research project was solely or principally designed to obtain a degree - and if yes, what degree.

| | | | | | | | What degree (multiple answers possible) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Primarily for degree | | MD/PhD thesis | | Master | | Other degree | |
| Type of research | Research details | Risk cat. | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Clinical trial | Medicinal products | A | 13 | 9.0 | 4 | 30.8 | 3 | 75.0 | | | 1 | 25.0 |
| | | B | 36 | 25.0 | 3 | 8.3 | 2 | 66.7 | 1 | 33.3 | | |
| | | C | 95 | 66.0 | 1 | 1.1 | 1 | 100.0 | | | | |
| | | All | 144 | 100.0 | 8 | 5.6 | 6 | 75.0 | 1 | 12.5 | 1 | 12.5 |
| | Medical devices | A | 50 | 79.4 | 13 | 26.0 | 8 | 61.5 | 6 | 46.2 | 1 | 7.7 |
| | | C | 13 | 20.6 | 2 | 15.4 | | | 1 | 50.0 | 1 | 50.0 |
| | | All | 63 | 100.0 | 15 | 23.8 | 8 | 53.3 | 7 | 46.7 | 2 | 13.3 |
| | Other clinical trials | A | 104 | 90.4 | 47 | 45.2 | 24 | 51.1 | 21 | 44.7 | 4 | 8.5 |
| | | B | 11 | 9.6 | 2 | 18.2 | 2 | 100.0 | | | | |
| | | All | 115 | 100.0 | 49 | 42.6 | 26 | 53.1 | 21 | 42.9 | 4 | 8.2 |
| | Combination drugs/devices | C | 1 | 100.0 | 1 | 100.0 | | | | | 1 | 100.0 |
| | | All | 1 | 100.0 | 1 | 100.0 | | | | | 1 | 100.0 |
| | Transplant products | C | 1 | 100.0 | | | | | | | | |
| | | All | 1 | 100.0 | | | | | | | | |
| | Gene therapy | All | 0 | | | | | | | | | |
| | Transplantation | All | 0 | | | | | | | | | |
| | All | All | 324 | 100.0 | 73 | 22.5 | 40 | 54.8 | 29 | 39.7 | 8 | 11.0 |
| Research w/ persons | | A | 461 | 97.5 | 198 | 43.0 | 94 | 47.5 | 102 | 51.5 | 8 | 4.0 |
| | | B | 12 | 2.5 | 2 | 16.7 | 2 | 100.0 | | | | |
| | | All | 473 | 100.0 | 200 | 42.3 | 96 | 48.0 | 102 | 51.0 | 8 | 4.0 |
| Further use | | n.a. | 566 | 100.0 | 279 | 49.3 | 128 | 45.9 | 145 | 52.0 | 16 | 5.7 |
| Deceased, embryos | | n.a. | 18 | 100.0 | 6 | 33.3 | 2 | 33.3 | 3 | 50.0 | 1 | 16.7 |
| Total number | | | 1381 | 100.0 | 558 | 40.4 | 266 | 47.7 | 279 | 50.0 | 33 | 5.9 |

Since multiple answers are possible, the row-wise percentages may sum up to a total over 100%.

### 4.3.4 Vulnerable persons

**Table 13:** Stratification of all approved projects by whether the research project involves any vulnerable persons - and if yes, what groups.

| | | | | | | What groups (multiple possible) | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Any vulnerable | | Healthy vol. | | Children | | Adolescents | | Unable to cons. | | Emergencies | | Others | |
| Type of research | Research details | Risk cat. | N | n | %row | n | %row | n | %row | n | %row | n | %row | n | %row | n | %row |
| Clinical trial | Medicinal products | A | 13 | 1 | 7.7 | 1 | 100.0 | | | | | | | | | | |
| | | B | 36 | 11 | 30.6 | 5 | 45.5 | 5 | 45.5 | 5 | 45.5 | | | | | | |
| | | C | 95 | 23 | 24.2 | 11 | 47.8 | 9 | 39.1 | 8 | 34.8 | 2 | 8.7 | 3 | 13.0 | | |
| | | All | 144 | 35 | 24.3 | 17 | 48.6 | 14 | 40.0 | 13 | 37.1 | 2 | 5.7 | 3 | 8.6 | | |
| | Medical devices | A | 50 | 11 | 22.0 | 5 | 45.5 | 3 | 27.3 | 3 | 27.3 | 2 | 18.2 | 2 | 18.2 | 1 | 9.1 |
| | | C | 13 | 4 | 30.8 | 3 | 75.0 | 1 | 25.0 | 1 | 25.0 | 1 | 25.0 | | | 1 | 25.0 |
| | | All | 63 | 15 | 23.8 | 8 | 53.3 | 4 | 26.7 | 4 | 26.7 | 3 | 20.0 | 2 | 13.3 | 2 | 13.3 |
| | Other clinical trials | A | 104 | 40 | 38.5 | 22 | 55.0 | 10 | 25.0 | 9 | 22.5 | 6 | 15.0 | 3 | 7.5 | 2 | 5.0 |
| | | B | 11 | 5 | 45.5 | 3 | 60.0 | 1 | 20.0 | 1 | 20.0 | 1 | 20.0 | 1 | 20.0 | | |
| | | All | 115 | 45 | 39.1 | 25 | 55.6 | 11 | 24.4 | 10 | 22.2 | 7 | 15.6 | 4 | 8.9 | 2 | 4.4 |
| | Combination drugs/devices | C | 1 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | | |
| | | All | 1 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | | |
| | Transplant products | C | 1 | | | | | | | | | | | | | | |
| | | All | 1 | | | | | | | | | | | | | | |
| | Gene therapy | All | 0 | | | | | | | | | | | | | | |
| | Transplantation | All | 0 | | | | | | | | | | | | | | |
| | All | All | 324 | 96 | 29.6 | 50 | 52.1 | 30 | 31.2 | 27 | 28.1 | 12 | 12.5 | 9 | 9.4 | 4 | 4.2 |
| Research w/ persons | | A | 461 | 198 | 43.0 | 101 | 51.0 | 59 | 29.8 | 61 | 30.8 | 15 | 7.6 | 15 | 7.6 | 20 | 10.1 |
| | | B | 12 | 5 | 41.7 | 3 | 60.0 | 1 | 20.0 | 1 | 20.0 | 1 | 20.0 | 1 | 20.0 | | |
| | | All | 473 | 203 | 42.9 | 104 | 51.2 | 60 | 29.6 | 62 | 30.5 | 16 | 7.9 | 16 | 7.9 | 20 | 9.9 |
| Further use | | n.a. | 566 | | | | | | | | | | | | | | |
| Deceased, embryos | | n.a. | 18 | | | | | | | | | | | | | | |
| Total number | | | 1381 | 299 | 21.7 | 154 | 51.5 | 90 | 30.1 | 89 | 29.8 | 28 | 9.4 | 25 | 8.4 | 24 | 8.0 |

Since multiple answers are possible, the row-wise percentages may sum up to a total over 100%.

### 4.3.5 Ionising radiation

**Table 14:** Stratification of clinical trials and research involving persons but not a clinical trial by involvement of ionising radiation.

| | | | | | Ionising radiation involved | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Total | | For imaging/control purposes | | As primary object of investigation | |
| Type of research | Research details | Risk cat. | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Clinical trial | Medicinal products | A | 13 | 9.0 | | | | |
| | | B | 36 | 25.0 | 11 | 30.6 | 2 | 5.6 |
| | | C | 95 | 66.0 | 37 | 38.9 | 3 | 3.2 |
| | | All | 144 | 100.0 | 48 | 33.3 | 5 | 3.5 |
| | Medical devices | A | 50 | 79.4 | 11 | 22.0 | 1 | 2.0 |
| | | C | 13 | 20.6 | 3 | 23.1 | | |
| | | All | 63 | 100.0 | 14 | 22.2 | 1 | 1.6 |
| | Other clinical trials | A | 104 | 90.4 | 8 | 7.7 | 2 | 1.9 |
| | | B | 11 | 9.6 | 4 | 36.4 | 1 | 9.1 |
| | | All | 115 | 100.0 | 12 | 10.4 | 3 | 2.6 |
| | Combination drugs/devices | C | 1 | 100.0 | | | | |
| | | All | 1 | 100.0 | | | | |
| | Transplant products | C | 1 | 100.0 | | | | |
| | | All | 1 | 100.0 | | | | |
| | Gene therapy | All | 0 | | | | | |
| | Transplantation | All | 0 | | | | | |
| | All | All | 324 | 100.0 | 74 | 22.8 | 9 | 2.8 |
| Research w/ persons | | A | 461 | 97.5 | 16 | 3.5 | | |
| | | B | 12 | 2.5 | 3 | 25.0 | | |
| | | n.a. | 473 | 100.0 | 19 | 4.0 | | |
| Total number | | | 797 | 100.0 | 93 | 11.7 | 9 | 1.1 |

### 4.3.6 Ethics committee

**Table 15:** Stratification of all approved projects by ethics committee.

| | | | | | Ethics committee | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | KEK-ZH | | EKNZ | | CER-VD | | KEK-BE | | CCER | | EKOS | | CE-TI | |
| Type of research | Research details | Risk cat. | N | %col | n | %col | n | %col | n | %col | n | %col | n | %col | n | %col | n | %col |
| Clinical trial | Medicinal products | A | 13 | 9.0 | 1 | 3.8 | 3 | 6.1 | 2 | 11.1 | 3 | 17.6 | 1 | 16.7 | 3 | 23.1 | | |
| | | B | 36 | 25.0 | 5 | 19.2 | 14 | 28.6 | 6 | 33.3 | 5 | 29.4 | 2 | 33.3 | 1 | 7.7 | 3 | 20.0 |
| | | C | 95 | 66.0 | 20 | 76.9 | 32 | 65.3 | 10 | 55.6 | 9 | 52.9 | 3 | 50.0 | 9 | 69.2 | 12 | 80.0 |
| | | All | 144 | 100.0 | 26 | 100.0 | 49 | 100.0 | 18 | 100.0 | 17 | 100.0 | 6 | 100.0 | 13 | 100.0 | 15 | 100.0 |
| | Medical devices | A | 50 | 79.4 | 18 | 78.3 | 10 | 83.3 | 4 | 66.7 | 7 | 63.6 | 4 | 100.0 | 4 | 100.0 | 3 | 100.0 |
| | | C | 13 | 20.6 | 5 | 21.7 | 2 | 16.7 | 2 | 33.3 | 4 | 36.4 | | | | | | |
| | | All | 63 | 100.0 | 23 | 100.0 | 12 | 100.0 | 6 | 100.0 | 11 | 100.0 | 4 | 100.0 | 4 | 100.0 | 3 | 100.0 |
| | Other clinical trials | A | 104 | 90.4 | 27 | 96.4 | 27 | 90.0 | 16 | 94.1 | 13 | 72.2 | 10 | 100.0 | 6 | 100.0 | 5 | 83.3 |
| | | B | 11 | 9.6 | 1 | 3.6 | 3 | 10.0 | 1 | 5.9 | 5 | 27.8 | | | | | 1 | 16.7 |
| | | All | 115 | 100.0 | 28 | 100.0 | 30 | 100.0 | 17 | 100.0 | 18 | 100.0 | 10 | 100.0 | 6 | 100.0 | 6 | 100.0 |
| | Combination drugs/devices | C | 1 | 100.0 | 1 | 100.0 | | | | | | | | | | | | |
| | | All | 1 | 100.0 | 1 | 100.0 | | | | | | | | | | | | |
| | Transplant products | C | 1 | 100.0 | 1 | 100.0 | | | | | | | | | | | | |
| | | All | 1 | 100.0 | 1 | 100.0 | | | | | | | | | | | | |
| | Gene therapy | All | | | | | | | | | | | | | | | | |
| | Transplantation | All | 0 | | | | | | | | | | | | | | | |
| | All | All | 324 | 100.0 | 79 | 100.0 | 91 | 100.0 | 41 | 100.0 | 46 | 100.0 | 20 | 100.0 | 23 | 100.0 | 24 | 100.0 |
| Research w/ persons | | A | 461 | 97.5 | 87 | 95.6 | 105 | 98.1 | 111 | 97.4 | 68 | 98.6 | 56 | 96.6 | 22 | 100.0 | 12 | 100.0 |
| | | B | 12 | 2.5 | 4 | 4.4 | 2 | 1.9 | 3 | 2.6 | 1 | 1.4 | 2 | 3.4 | | | | |
| | | All | 473 | 100.0 | 91 | 100.0 | 107 | 100.0 | 114 | 100.0 | 69 | 100.0 | 58 | 100.0 | 22 | 100.0 | 12 | 100.0 |
| Further use | | n.a. | 566 | 100.0 | 174 | 100.0 | 117 | 100.0 | 109 | 100.0 | 91 | 100.0 | 45 | 100.0 | 19 | 100.0 | 11 | 100.0 |
| Deceased, embryos | | n.a. | 18 | 100.0 | 4 | 100.0 | 7 | 100.0 | 2 | 100.0 | | | 5 | 100.0 | | | | |
| Total number | | | 1381 | 100.0 | 348 | 100.0 | 322 | 100.0 | 266 | 100.0 | 206 | 100.0 | 128 | 100.0 | 64 | 100.0 | 47 | 100.0 |

### 4.3.7 Application procedure

**Table 16:** Stratification of all approved projects by characteristics of the application procedure.

| | | | | | Review procedure | | | | | | First decision | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Ordinary | | Simplified | | Presidential | | Approved | | Charges | | Conditions | | Declined | | Non-consid. | |
| Type of research | Research details | Risk cat. | N | %col | n | %row | n | %row | n | %row | n | %row | n | %row | n | %row | n | %row | n | %row |
| Clinical trial | Medicinal products | A | 13 | 9.0 | 4 | 30.8 | 9 | 69.2 | | | | | 5 | 38.5 | 8 | 61.5 | | | | |
| | | B | 36 | 25.0 | 34 | 94.4 | 2 | 5.6 | | | 1 | 2.8 | 13 | 36.1 | 22 | 61.1 | | | | |
| | | C | 95 | 66.0 | 93 | 97.9 | 2 | 2.1 | | | 3 | 3.2 | 35 | 36.8 | 56 | 58.9 | | | 1 | 1.1 |
| | | All | 144 | 100.0 | 131 | 91.0 | 13 | 9.0 | | | 4 | 2.8 | 53 | 36.8 | 86 | 59.7 | | | 1 | 0.7 |
| | Medical devices | A | 50 | 79.4 | 4 | 8.0 | 46 | 92.0 | | | 3 | 6.0 | 11 | 22.0 | 36 | 72.0 | | | | |
| | | C | 13 | 20.6 | 13 | 100.0 | | | | | | | | | 13 | 100.0 | | | | |
| | | All | 63 | 100.0 | 17 | 27.0 | 46 | 73.0 | | | 3 | 4.8 | 11 | 17.5 | 49 | 77.8 | | | | |
| | Other clinical trials | A | 104 | 90.4 | 16 | 15.4 | 88 | 84.6 | | | 4 | 3.8 | 33 | 31.7 | 67 | 64.4 | | | | |
| | | B | 11 | 9.6 | 10 | 90.9 | 1 | 9.1 | | | | | 3 | 27.3 | 8 | 72.7 | | | | |
| | | All | 115 | 100.0 | 26 | 22.6 | 89 | 77.4 | | | 4 | 3.5 | 36 | 31.3 | 75 | 65.2 | | | | |
| | Combination drugs/devices | C | 1 | 100.0 | 1 | 100.0 | | | | | | | | | 1 | 100.0 | | | | |
| | | All | 1 | 100.0 | 1 | 100.0 | | | | | | | | | 1 | 100.0 | | | | |
| | Transplant products | C | 1 | 100.0 | 1 | 100.0 | | | | | | | | | 1 | 100.0 | | | | |
| | | All | 1 | 100.0 | 1 | 100.0 | | | | | | | | | 1 | 100.0 | | | | |
| | Gene therapy | All | 0 | | | | | | | | | | | | | | | | | |
| | Transplantation | All | 0 | | | | | | | | | | | | | | | | | |
| | All | All | 324 | 100.0 | 176 | 54.3 | 148 | 45.7 | | | 11 | 3.4 | 100 | 30.9 | 212 | 65.4 | | | 1 | 0.3 |
| Research w/ persons | | A | 461 | 97.5 | 26 | 5.6 | 423 | 91.8 | 12 | 2.6 | 33 | 7.2 | 187 | 40.6 | 239 | 51.8 | 1 | 0.2 | 1 | 0.2 |
| | | B | 12 | 2.5 | 10 | 83.3 | 2 | 16.7 | | | | | 2 | 16.7 | 10 | 83.3 | | | | |
| | | All | 473 | 100.0 | 36 | 7.6 | 425 | 89.9 | 12 | 2.5 | 33 | 7.0 | 189 | 40.0 | 249 | 52.6 | 1 | 0.2 | 1 | 0.2 |
| Further use | | n.a. | 566 | 100.0 | 13 | 2.3 | 443 | 78.3 | 110 | 19.4 | 174 | 30.7 | 188 | 33.2 | 203 | 35.9 | 1 | 0.2 | | |
| Deceased, embryos | | n.a. | 18 | 100.0 | | | 17 | 94.4 | 1 | 5.6 | 4 | 22.2 | 11 | 61.1 | 3 | 16.7 | | | | |
| Total number | | | 1381 | 100.0 | 225 | 16.3 | 1033 | 74.8 | 123 | 8.9 | 222 | 16.1 | 488 | 35.3 | 667 | 48.3 | 2 | 0.1 | 2 | 0.1 |

CE-TI reviews all projects in an 'Ordinary procedure'.

## 4.4 Subgroups of research projects

### 4.4.1 Subgroup “Clinical trials” - research covered by the ClinO

#### 4.4.1.1 Project characteristics used as stratification variables of clinical trials

The allowed answers of project characteristics according to the entry mask of BASEC are reported below. No further explanations are provided in BASEC. Since not all project characteristics are appropriate or meaningful for certain subgroups, the BASEC web portal applies logical filtering.

**Allocation:** Single choice field with allowed answers: “Randomised controlled trial”, “Non-randomised controlled trial” and “Not applicable”.

**Masking technique:** Single choice field with allowed answers: “Open”, “Single-blind”, “Double-blind”.

**Type of control:** Single choice field with allowed answers: “Placebo”, “Active”, “Before-after (historic)”, “Dosage comparison”, “None”.

**Participant arms/distribution:** Single choice field to indicate the trial participant arms / distribution with allowed answers: “Single-armed”, “Parallel groups”, “Cross-over”, “Factorial”, “Other or n/a”

**Phase:** This question is only asked for drug and drug/device combination trials. Single choice field with allowed answers: “Phase 1”, “Phase 1/2”, “Phase 2”, “Phase 3”, “Phase 4”, “n/a”. During post-processing “Phase 1” and “Phase 1/2” were assigned to “Phase 1”.

**First in man:** Single choice field (“Yes”, “No”). This question is only asked for drug, device and drug/device combination trials.

**Standard use in medical device trials:** The first question is “Does your project only involve standard use of existing medical devices with conformity marking?”. If the answer is “No”, the answer can be further specified: “New use of existing device” (i.e. a CE-marked medical device used outside of the intended use), “New medical device” (i.e. a medical device that has no CE-marking).

**Type of research project in projects covered by HRO Chapter 2** Single choice field with allowed answers: “Cohort study”, “Registry / Quality control” (only quality control studies under the HRA), “Case control study” and “Other or n/a”. The last group also includes projects declared as “Observational study” before this option was disabled on August 21, 2017.

### 4.4.1.2 Stratification of 'Clinical trials'

**Table 17:** Stratification of **all clinical trials** by risk category, study design and initiator of the research project. The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

| | | | | | Risk category | | | | | | Study design | | | | | | Initiator | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | A | | B | | C | | Mono | | Multi CH | | Multi Int. | | Industry | | Investigator | |
| Allocation | Control | Masking | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Randomised controlled | Active | Open | 56 | 26.3 | 30 | 53.6 | 11 | 19.6 | 15 | 26.8 | 22 | 39.3 | 4 | 7.1 | 30 | 53.6 | 20 | 35.7 | 36 | 64.3 |
| | | Double-blind | 12 | 5.6 | 5 | 41.7 | 3 | 25.0 | 4 | 33.3 | 3 | 25.0 | 1 | 8.3 | 8 | 66.7 | 5 | 41.7 | 7 | 58.3 |
| | | Single-blind | 24 | 11.3 | 21 | 87.5 | 1 | 4.2 | 2 | 8.3 | 14 | 58.3 | 5 | 20.8 | 5 | 20.8 | 3 | 12.5 | 21 | 87.5 |
| | Placebo | Open | 1 | 0.5 | | | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | Double-blind | 72 | 33.8 | 14 | 19.4 | 19 | 26.4 | 39 | 54.2 | 26 | 36.1 | 9 | 12.5 | 37 | 51.4 | 38 | 52.8 | 34 | 47.2 |
| | | Single-blind | 6 | 2.8 | 4 | 66.7 | 1 | 16.7 | 1 | 16.7 | 2 | 33.3 | | | 4 | 66.7 | 3 | 50.0 | 3 | 50.0 |
| | Before/after | Open | 4 | 1.9 | 3 | 75.0 | 1 | 25.0 | | | 2 | 50.0 | | | 2 | 50.0 | 2 | 50.0 | 2 | 50.0 |
| | | Double-blind | 2 | 0.9 | 2 | 100.0 | | | | | 2 | 100.0 | | | | | | | 2 | 100.0 |
| | | Single-blind | 4 | 1.9 | 4 | 100.0 | | | | | 4 | 100.0 | | | | | | | 4 | 100.0 |
| | Dosage | Open | 5 | 2.3 | 1 | 20.0 | 1 | 20.0 | 3 | 60.0 | 2 | 40.0 | | | 3 | 60.0 | 4 | 80.0 | 1 | 20.0 |
| | | Double-blind | 4 | 1.9 | 1 | 25.0 | | | 3 | 75.0 | 1 | 25.0 | | | 3 | 75.0 | 4 | 100.0 | | |
| | | Single-blind | 2 | 0.9 | 2 | 100.0 | | | | | 2 | 100.0 | | | | | | | 2 | 100.0 |
| | None | Open | 16 | 7.5 | 14 | 87.5 | 1 | 6.2 | 1 | 6.2 | 9 | 56.2 | 3 | 18.8 | 4 | 25.0 | | | 16 | 100.0 |
| | | Double-blind | 2 | 0.9 | 2 | 100.0 | | | | | 2 | 100.0 | | | | | | | 2 | 100.0 |
| | | Single-blind | 3 | 1.4 | 3 | 100.0 | | | | | 3 | 100.0 | | | | | | | 3 | 100.0 |
| | | All | 213 | 100.0 | 106 | 49.8 | 39 | 18.3 | 68 | 31.9 | 95 | 44.6 | 22 | 10.3 | 96 | 45.1 | 79 | 37.1 | 134 | 62.9 |
| Non-random. controlled | Active | Open | 6 | 21.4 | 5 | 83.3 | 1 | 16.7 | | | 4 | 66.7 | | | 2 | 33.3 | 2 | 33.3 | 4 | 66.7 |
| | | Single-blind | 1 | 3.6 | 1 | 100.0 | | | | | | | 1 | 100.0 | | | | | 1 | 100.0 |
| | Before/after | Open | 3 | 10.7 | 1 | 33.3 | 1 | 33.3 | 1 | 33.3 | 3 | 100.0 | | | | | | | 3 | 100.0 |
| | None | Open | 18 | 64.3 | 6 | 33.3 | 1 | 5.6 | 11 | 61.1 | 5 | 27.8 | 1 | 5.6 | 12 | 66.7 | 10 | 55.6 | 8 | 44.4 |
| | | All | 28 | 100.0 | 13 | 46.4 | 3 | 10.7 | 12 | 42.9 | 12 | 42.9 | 2 | 7.1 | 14 | 50.0 | 12 | 42.9 | 16 | 57.1 |
| Not applicable | Active | Open | 3 | 3.6 | 2 | 66.7 | | | 1 | 33.3 | 2 | 66.7 | | | 1 | 33.3 | 1 | 33.3 | 2 | 66.7 |
| | | Single-blind | 3 | 3.6 | 3 | 100.0 | | | | | 3 | 100.0 | | | | | 2 | 66.7 | 1 | 33.3 |
| | Placebo | Open | 1 | 1.2 | 1 | 100.0 | | | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | Before/after | Open | 5 | 6.0 | 5 | 100.0 | | | | | 5 | 100.0 | | | | | | | 5 | 100.0 |
| | | Single-blind | 2 | 2.4 | 2 | 100.0 | | | | | 2 | 100.0 | | | | | | | 2 | 100.0 |
| | Dosage | Open | 4 | 4.8 | 1 | 25.0 | 1 | 25.0 | 2 | 50.0 | 2 | 50.0 | | | 2 | 50.0 | 2 | 50.0 | 2 | 50.0 |
| | | Double-blind | 1 | 1.2 | | | | | 1 | 100.0 | | | | | 1 | 100.0 | 1 | 100.0 | | |
| | None | Open | 61 | 73.5 | 31 | 50.8 | 4 | 6.6 | 26 | 42.6 | 32 | 52.5 | 3 | 4.9 | 26 | 42.6 | 28 | 45.9 | 33 | 54.1 |
| | | Single-blind | 3 | 3.6 | 3 | 100.0 | | | | | 3 | 100.0 | | | | | | | 3 | 100.0 |
| | | All | 83 | 100.0 | 48 | 57.8 | 5 | 6.0 | 30 | 36.1 | 50 | 60.2 | 3 | 3.6 | 30 | 36.1 | 34 | 41.0 | 49 | 59.0 |
| Total number | | | 324 | 100.0 | 167 | 51.5 | 47 | 14.5 | 110 | 34.0 | 157 | 48.5 | 27 | 8.3 | 140 | 43.2 | 125 | 38.6 | 199 | 61.4 |

Note that some categories of 'Control' are not meaningful for certain subtype of clinical trials (e.g. dosage for medical device).

**Table 18:** Stratification of **all clinical trials** by participant arms/distribution.

| | | | | | Participant arms/distribution | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Single-arm | | Parallel groups | | Crossover | | Factorial | | Other or n/a | |
| **Allocation** | **Control** | **Masking** | **N** | **%col** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** |
| Randomised controlled | Active | Open | 56 | 26.3 | | | 45 | 80.4 | 8 | 14.3 | | | 3 | 5.4 |
| | | Double-blind | 12 | 5.6 | 1 | 8.3 | 10 | 83.3 | 1 | 8.3 | | | | |
| | | Single-blind | 24 | 11.3 | | | 21 | 87.5 | 2 | 8.3 | | | 1 | 4.2 |
| | Placebo | Open | 1 | 0.5 | | | | | 1 | 100.0 | | | | |
| | | Double-blind | 72 | 33.8 | 1 | 1.4 | 57 | 79.2 | 12 | 16.7 | | | 2 | 2.8 |
| | | Single-blind | 6 | 2.8 | | | 5 | 83.3 | 1 | 16.7 | | | | |
| | Before/after | Open | 4 | 1.9 | | | 4 | 100.0 | | | | | | |
| | | Double-blind | 2 | 0.9 | 1 | 50.0 | 1 | 50.0 | | | | | | |
| | | Single-blind | 4 | 1.9 | | | 4 | 100.0 | | | | | | |
| | Dosage | Open | 5 | 2.3 | | | 4 | 80.0 | 1 | 20.0 | | | | |
| | | Double-blind | 4 | 1.9 | 1 | 25.0 | 3 | 75.0 | | | | | | |
| | | Single-blind | 2 | 0.9 | | | 1 | 50.0 | 1 | 50.0 | | | | |
| | None | Open | 16 | 7.5 | 1 | 6.2 | 8 | 50.0 | 5 | 31.2 | | | 2 | 12.5 |
| | | Double-blind | 2 | 0.9 | 1 | 50.0 | 1 | 50.0 | | | | | | |
| | | Single-blind | 3 | 1.4 | | | 3 | 100.0 | | | | | | |
| | | All | 213 | 100.0 | 6 | 2.8 | 167 | 78.4 | 32 | 15.0 | | | 8 | 3.8 |
| Non-random. controlled | Active | Open | 6 | 21.4 | 1 | 16.7 | 2 | 33.3 | | | | | 3 | 50.0 |
| | | Single-blind | 1 | 3.6 | | | | | 1 | 100.0 | | | | |
| | Before/after | Open | 3 | 10.7 | 1 | 33.3 | 1 | 33.3 | | | | | 1 | 33.3 |
| | None | Open | 18 | 64.3 | 9 | 50.0 | 3 | 16.7 | 1 | 5.6 | | | 5 | 27.8 |
| | | All | 28 | 100.0 | 11 | 39.3 | 6 | 21.4 | 2 | 7.1 | | | 9 | 32.1 |
| Not applicable | Active | Open | 3 | 3.6 | 1 | 33.3 | | | | | | | 2 | 66.7 |
| | | Single-blind | 3 | 3.6 | | | | | 2 | 66.7 | | | 1 | 33.3 |
| | Placebo | Open | 1 | 1.2 | | | | | | | 1 | 100.0 | | |
| | Before/after | Open | 5 | 6.0 | 2 | 40.0 | | | 1 | 20.0 | | | 2 | 40.0 |
| | | Single-blind | 2 | 2.4 | 1 | 50.0 | | | 1 | 50.0 | | | | |
| | Dosage | Open | 4 | 4.8 | | | 2 | 50.0 | | | | | 2 | 50.0 |
| | | Double-blind | 1 | 1.2 | | | 1 | 100.0 | | | | | | |
| | None | Open | 61 | 73.5 | 33 | 54.1 | 6 | 9.8 | 2 | 3.3 | | | 20 | 32.8 |
| | | Single-blind | 3 | 3.6 | 3 | 100.0 | | | | | | | | |
| | | All | 83 | 100.0 | 40 | 48.2 | 9 | 10.8 | 6 | 7.2 | 1 | 1.2 | 27 | 32.5 |
| Total number | | | 324 | 100.0 | 57 | 17.6 | 182 | 56.2 | 40 | 12.3 | 1 | 0.3 | 44 | 13.6 |

### 4.4.2 Subgroups of "Clinical trials"

**Table 19:** Overview of type of clinical trial.

| Type of clinical trial | Legal basis (ClinO) | n | $\%_{col}$ |
|---|---|---|---|
| Medicinal products | Art 19 | 144 | 44.4 |
| Medical devices | Art 20 | 63 | 19.4 |
| Other clinical trials | Art 61 | 115 | 35.5 |
| Combination drugs/devices [1] | | 1 | 0.3 |
| Transplant products | Art 21 | 1 | 0.3 |
| Gene therapy | Art 22 | 0 | 0.0 |
| Transplantation | Art 49 | 0 | 0.0 |
| Total number | | 324 | 100.0 |

[1] Combination of medical device and medical product: this category is BASEC-specific.

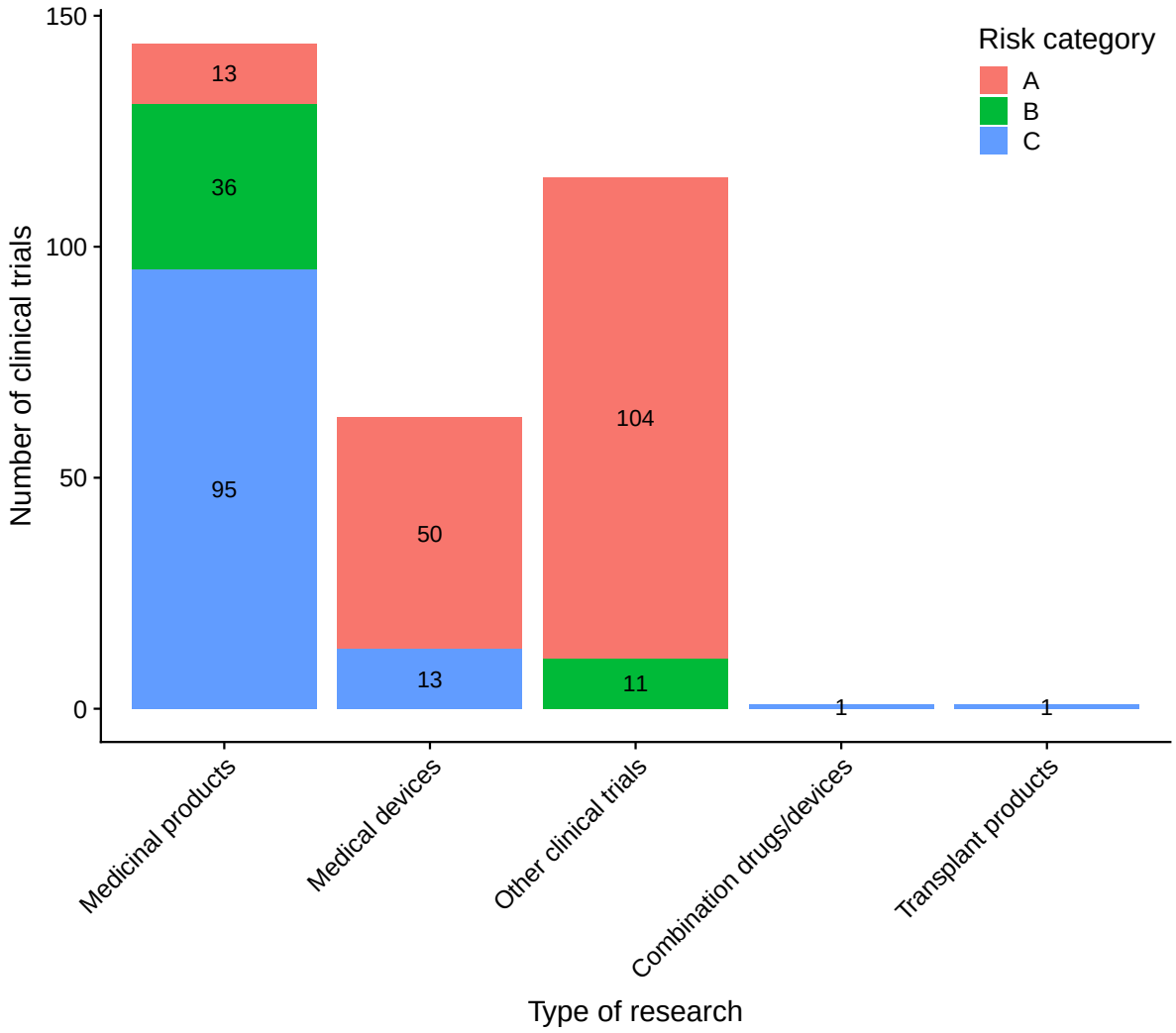


**Figure 5:** Stratification of all clinical trials by type of trial and risk category.

**Description of distinctive features of the results:**

As expected, a large fraction of the trials on medicinal products are international multi-center studies from industry. The majority of medical device trials involve standard use of the device (risk category A), are mono-centric and investigator initiated trials.

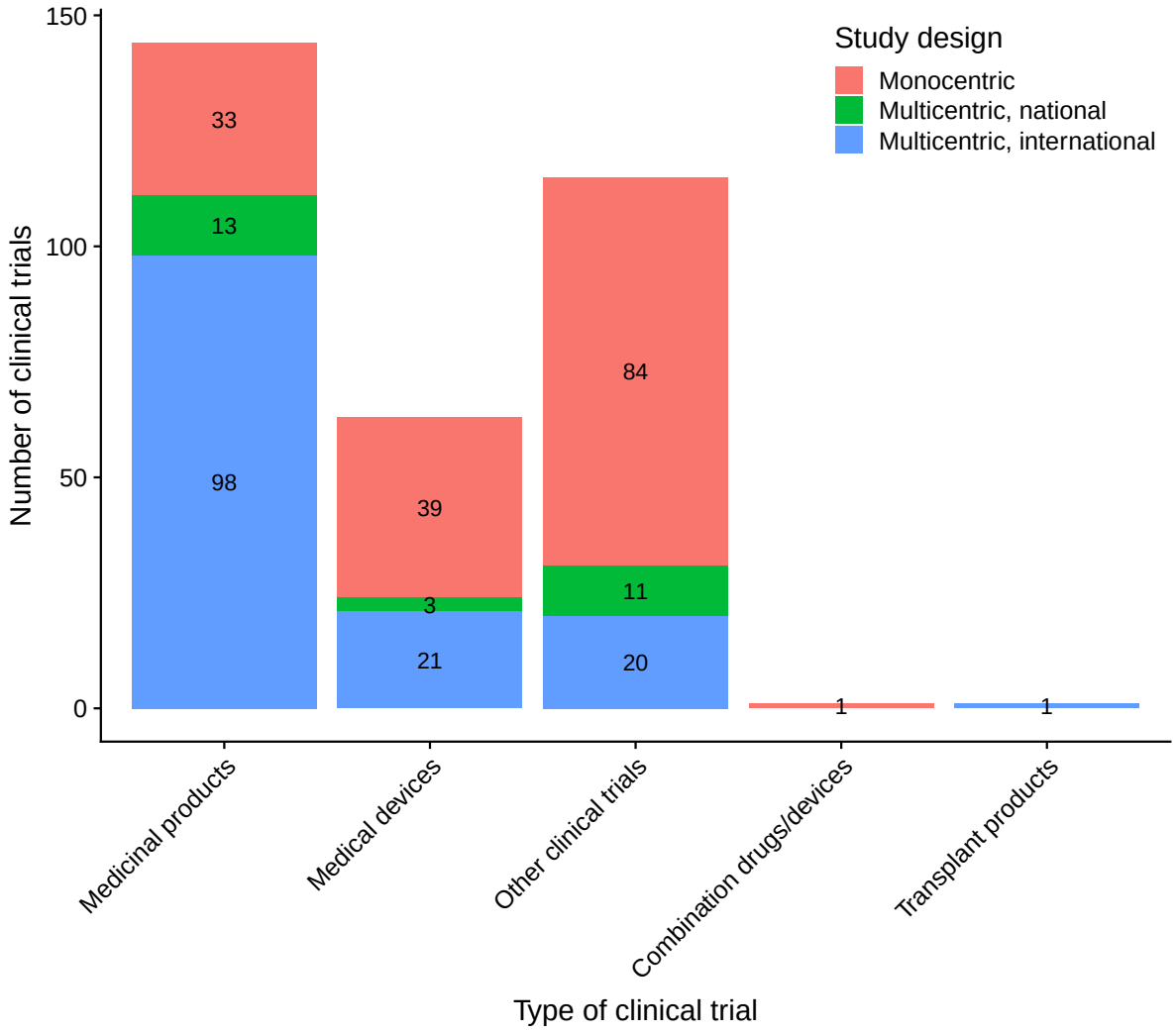


**Figure 6:** Stratification of all clinical trials by type of trial and study design.

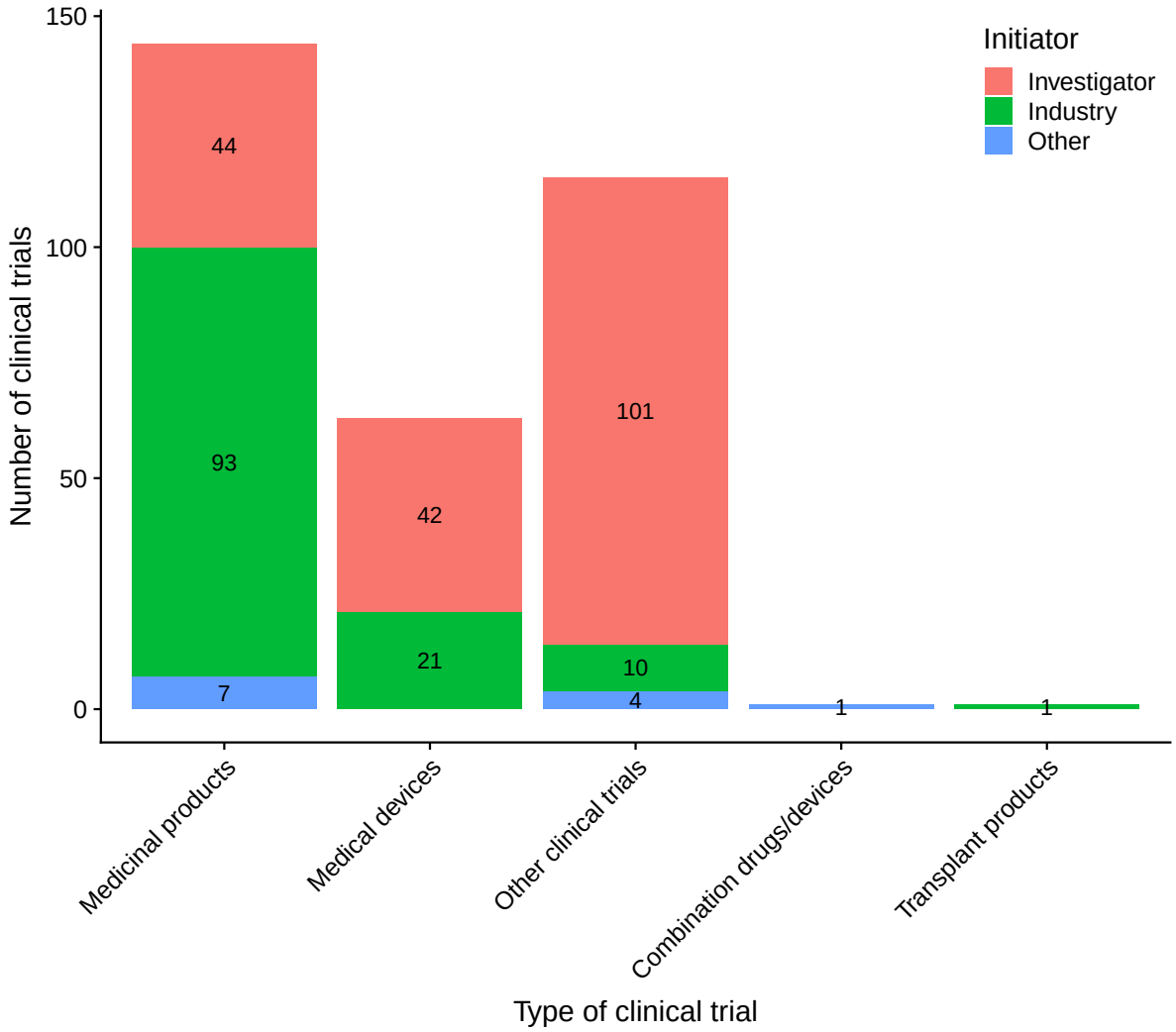


**Figure 7:** Stratification of all clinical trials by type of trial and initiator.

### 4.4.2.1 Subgroup "Medicinal products trials" (ClinO Art 19)

**Table 20:** Stratification of **medicinal products trials** by risk category, study design and initiator of the research project. The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

| | | | | | Risk category | | | | | | Study design | | | | | | Initiator | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | A | | B | | C | | Mono | | Multi CH | | Multi Int. | | Industry | | Investigator | |
| **Allocation** | **Control** | **Masking** | **N** | **%col** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** |
| Randomised controlled | Active | Open | 26 | 25.5 | 4 | 15.4 | 7 | 26.9 | 15 | 57.7 | 6 | 23.1 | 3 | 11.5 | 17 | 65.4 | 15 | 57.7 | 11 | 42.3 |
| | | Double-blind | 8 | 7.8 | 2 | 25.0 | 2 | 25.0 | 4 | 50.0 | 1 | 12.5 | 1 | 12.5 | 6 | 75.0 | 5 | 62.5 | 3 | 37.5 |
| | | Single-blind | 1 | 1.0 | | | | | 1 | 100.0 | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | Placebo | Double-blind | 56 | 54.9 | 2 | 3.6 | 17 | 30.4 | 37 | 66.1 | 15 | 26.8 | 5 | 8.9 | 36 | 64.3 | 35 | 62.5 | 21 | 37.5 |
| | | Single-blind | 2 | 2.0 | | | 1 | 50.0 | 1 | 50.0 | | | | | 2 | 100.0 | 2 | 100.0 | | |
| | Before/after | Open | 1 | 1.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 | 1 | 100.0 | | |
| | Dosage | Open | 4 | 3.9 | | | 1 | 25.0 | 3 | 75.0 | 1 | 25.0 | | | 3 | 75.0 | 4 | 100.0 | | |
| | | Double-blind | 3 | 2.9 | | | | | 3 | 100.0 | | | | | 3 | 100.0 | 3 | 100.0 | | |
| | None | Open | 1 | 1.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 | | | 1 | 100.0 |
| | | All | 102 | 100.0 | 8 | 7.8 | 30 | 29.4 | 64 | 62.7 | 24 | 23.5 | 9 | 8.8 | 69 | 67.6 | 65 | 63.7 | 37 | 36.3 |
| Non-random. controlled | Active | Open | 1 | 8.3 | | | 1 | 100.0 | | | | | | | 1 | 100.0 | 1 | 100.0 | | |
| | Before/after | Open | 1 | 8.3 | | | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | None | Open | 10 | 83.3 | 2 | 20.0 | | | 8 | 80.0 | | | 1 | 10.0 | 9 | 90.0 | 7 | 70.0 | 3 | 30.0 |
| | | All | 12 | 100.0 | 2 | 16.7 | 2 | 16.7 | 8 | 66.7 | 1 | 8.3 | 1 | 8.3 | 10 | 83.3 | 8 | 66.7 | 4 | 33.3 |
| Not applicable | Active | Open | 1 | 3.2 | | | | | 1 | 100.0 | | | | | 1 | 100.0 | 1 | 100.0 | | |
| | Before/after | Open | 1 | 3.2 | 1 | 100.0 | | | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | Dosage | Open | 3 | 9.7 | | | 1 | 33.3 | 2 | 66.7 | 1 | 33.3 | | | 2 | 66.7 | 2 | 66.7 | 1 | 33.3 |
| | | Double-blind | 1 | 3.2 | | | | | 1 | 100.0 | | | | | 1 | 100.0 | 1 | 100.0 | | |
| | None | Open | 25 | 80.6 | 2 | 8.0 | 3 | 12.0 | 20 | 80.0 | 7 | 28.0 | 3 | 12.0 | 15 | 60.0 | 16 | 64.0 | 9 | 36.0 |
| | | All | 31 | 100.0 | 3 | 9.7 | 4 | 12.9 | 24 | 77.4 | 9 | 29.0 | 3 | 9.7 | 19 | 61.3 | 20 | 64.5 | 11 | 35.5 |
| Total number | | | 145 | 100.0 | 13 | 9.0 | 36 | 24.8 | 96 | 66.2 | 34 | 23.4 | 13 | 9.0 | 98 | 67.6 | 93 | 64.1 | 52 | 35.9 |

The total number of 145 research projects consist of 144 medicinal product trials and 1 trials on a combination medicinal product and medical device.

**Table 21:** Stratification of **medicinal products trials** by phase and whether 'first in man'.

| | | | | | Phase [1] | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | 1 | | 2 | | 3 | | 4 | | n/a | | First in man [2] | |
| **Allocation** | **Control** | **Masking** | **N** | **%col** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** |
| Randomised controlled | Active | Open | 26 | 25.5 | 4 | 15.4 | 6 | 23.1 | 12 | 46.2 | 3 | 11.5 | 1 | 3.8 | | |
| | | Double-blind | 8 | 7.8 | | | | | 5 | 62.5 | 3 | 37.5 | | | | |
| | | Single-blind | 1 | 1.0 | | | 1 | 100.0 | | | | | | | | |
| | Placebo | Double-blind | 56 | 54.9 | 3 | 5.4 | 16 | 28.6 | 29 | 51.8 | 3 | 5.4 | 5 | 8.9 | | |
| | | Single-blind | 2 | 2.0 | | | 1 | 50.0 | 1 | 50.0 | | | | | | |
| | Before/after | Open | 1 | 1.0 | | | | | | | 1 | 100.0 | | | | |
| | Dosage | Open | 4 | 3.9 | 1 | 25.0 | 1 | 25.0 | 2 | 50.0 | | | | | | |
| | | Double-blind | 3 | 2.9 | | | 2 | 66.7 | 1 | 33.3 | | | | | | |
| | None | Open | 1 | 1.0 | | | | | 1 | 100.0 | | | | | | |
| | | All | 102 | 100.0 | 8 | 7.8 | 27 | 26.5 | 51 | 50.0 | 10 | 9.8 | 6 | 5.9 | | |
| Non-random. controlled | Active | Open | 1 | 8.3 | | | | | 1 | 100.0 | | | | | | |
| | Before/after | Open | 1 | 8.3 | | | | | | | 1 | 100.0 | | | | |
| | None | Open | 10 | 83.3 | 4 | 40.0 | 3 | 30.0 | 1 | 10.0 | 2 | 20.0 | | | | |
| | | All | 12 | 100.0 | 4 | 33.3 | 3 | 25.0 | 2 | 16.7 | 3 | 25.0 | | | | |
| Not applicable | Active | Open | 1 | 3.2 | | | | | 1 | 100.0 | | | | | | |
| | Before/after | Open | 1 | 3.2 | | | 1 | 100.0 | | | | | | | | |
| | Dosage | Open | 3 | 9.7 | 3 | 100.0 | | | | | | | | | 3 | 100.0 |
| | | Double-blind | 1 | 3.2 | | | | | 1 | 100.0 | | | | | | |
| | None | Open | 25 | 80.6 | 13 | 52.0 | 5 | 20.0 | 4 | 16.0 | 1 | 4.0 | 2 | 8.0 | 3 | 12.0 |
| | | All | 31 | 100.0 | 16 | 51.6 | 6 | 19.4 | 6 | 19.4 | 1 | 3.2 | 2 | 6.5 | 6 | 19.4 |
| Total number | | | 145 | 100.0 | 28 | 19.3 | 36 | 24.8 | 59 | 40.7 | 14 | 9.7 | 8 | 5.5 | 6 | 4.1 |

[1] In this table the two categories 'phase 1' and 'phase 1/2' are grouped to 'phase 1'.
[2] 'First in man' can be selected for phase 1 and 1/2 studies as well as studies without a defined phase ('n/a').

**Table 22:** Stratification of **medicinal products trials** by participant arms/distribution.

| | | | | | Participant arms/distribution | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Single-arm | | Parallel groups | | Crossover | | Other or n/a | |
| **Allocation** | **Control** | **Masking** | **N** | **%col** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** |
| Randomised controlled | Active | Open | 26 | 25.5 | | | 21 | 80.8 | 5 | 19.2 | | |
| | | Double-blind | 8 | 7.8 | | | 8 | 100.0 | | | | |
| | | Single-blind | 1 | 1.0 | | | 1 | 100.0 | | | | |
| | Placebo | Double-blind | 56 | 54.9 | | | 47 | 83.9 | 7 | 12.5 | 2 | 3.6 |
| | | Single-blind | 2 | 2.0 | | | 2 | 100.0 | | | | |
| | Before/after | Open | 1 | 1.0 | | | 1 | 100.0 | | | | |
| | Dosage | Open | 4 | 3.9 | | | 3 | 75.0 | 1 | 25.0 | | |
| | | Double-blind | 3 | 2.9 | 1 | 33.3 | 2 | 66.7 | | | | |
| | None | Open | 1 | 1.0 | | | 1 | 100.0 | | | | |
| | | All | 102 | 100.0 | 1 | 1.0 | 86 | 84.3 | 13 | 12.7 | 2 | 2.0 |
| Non-random. controlled | Active | Open | 1 | 8.3 | 1 | 100.0 | | | | | | |
| | Before/after | Open | 1 | 8.3 | 1 | 100.0 | | | | | | |
| | None | Open | 10 | 83.3 | 5 | 50.0 | 2 | 20.0 | | | 3 | 30.0 |
| | | All | 12 | 100.0 | 7 | 58.3 | 2 | 16.7 | | | 3 | 25.0 |
| Not applicable | Active | Open | 1 | 3.2 | | | | | | | 1 | 100.0 |
| | Before/after | Open | 1 | 3.2 | 1 | 100.0 | | | | | | |
| | Dosage | Open | 3 | 9.7 | | | 2 | 66.7 | | | 1 | 33.3 |
| | | Double-blind | 1 | 3.2 | | | 1 | 100.0 | | | | |
| | None | Open | 25 | 80.6 | 13 | 52.0 | 6 | 24.0 | | | 6 | 24.0 |
| | | All | 31 | 100.0 | 14 | 45.2 | 9 | 29.0 | | | 8 | 25.8 |
| Total number | | | 145 | 100.0 | 22 | 15.2 | 97 | 66.9 | 13 | 9.0 | 13 | 9.0 |

### 4.4.2.2 Subgroup "Medical device trials" (ClinO Art 20)

**Table 23:** Stratification of **medical device trials** by risk category, study design and initiator of the research project. The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

| | | | | | Risk category | | | | Study design | | | | | | Initiator | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | A | | C | | Mono | | Multi CH | | Multi Int. | | Industry | | Investigator | |
| **Allocation** | **Control** | **Masking** | **N** | **%col** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** |
| Randomised controlled | Active | Open | 9 | 31.0 | 9 | 100.0 | | | 5 | 55.6 | | | 4 | 44.4 | 3 | 33.3 | 6 | 66.7 |
| | | Double-blind | 2 | 6.9 | 2 | 100.0 | | | 1 | 50.0 | | | 1 | 50.0 | | | 2 | 100.0 |
| | | Single-blind | 6 | 20.7 | 5 | 83.3 | 1 | 16.7 | 2 | 33.3 | 1 | 16.7 | 3 | 50.0 | 2 | 33.3 | 4 | 66.7 |
| | Placebo | Double-blind | 4 | 13.8 | 3 | 75.0 | 1 | 25.0 | 2 | 50.0 | 2 | 50.0 | | | 1 | 25.0 | 3 | 75.0 |
| | | Single-blind | 2 | 6.9 | 2 | 100.0 | | | | | | | 2 | 100.0 | 1 | 50.0 | 1 | 50.0 |
| | Before/after | Double-blind | 1 | 3.4 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | None | Open | 3 | 10.3 | 2 | 66.7 | 1 | 33.3 | 3 | 100.0 | | | | | | | 3 | 100.0 |
| | | Double-blind | 1 | 3.4 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | Single-blind | 1 | 3.4 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | All | 29 | 100.0 | 26 | 89.7 | 3 | 10.3 | 16 | 55.2 | 3 | 10.3 | 10 | 34.5 | 7 | 24.1 | 22 | 75.9 |
| Non-random. controlled | Active | Open | 1 | 14.3 | 1 | 100.0 | | | 1 | 100.0 | | | | | 1 | 100.0 | | |
| | Before/after | Open | 2 | 28.6 | 1 | 50.0 | 1 | 50.0 | 2 | 100.0 | | | | | | | 2 | 100.0 |
| | None | Open | 4 | 57.1 | 1 | 25.0 | 3 | 75.0 | 1 | 25.0 | | | 3 | 75.0 | 3 | 75.0 | 1 | 25.0 |
| | | All | 7 | 100.0 | 3 | 42.9 | 4 | 57.1 | 4 | 57.1 | | | 3 | 42.9 | 4 | 57.1 | 3 | 42.9 |
| Not applicable | Active | Open | 1 | 3.6 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | Single-blind | 3 | 10.7 | 3 | 100.0 | | | 3 | 100.0 | | | | | 2 | 66.7 | 1 | 33.3 |
| | Before/after | Open | 1 | 3.6 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | Single-blind | 1 | 3.6 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | Dosage | Open | 1 | 3.6 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | None | Open | 19 | 67.9 | 12 | 63.2 | 7 | 36.8 | 11 | 57.9 | | | 8 | 42.1 | 8 | 42.1 | 11 | 57.9 |
| | | Single-blind | 2 | 7.1 | 2 | 100.0 | | | 2 | 100.0 | | | | | | | 2 | 100.0 |
| | | All | 28 | 100.0 | 21 | 75.0 | 7 | 25.0 | 20 | 71.4 | | | 8 | 28.6 | 10 | 35.7 | 18 | 64.3 |
| Total number | | | 64 | 100.0 | 50 | 78.1 | 14 | 21.9 | 40 | 62.5 | 3 | 4.7 | 21 | 32.8 | 21 | 32.8 | 43 | 67.2 |

The total number of 64 research projects consist of 63 medical device trials and 1 trials on a combination medicinal product and medical device.

**Table 24:** Stratification of **medical device trials** by participant arms/distribution.

| | | | | | Participant arms/distribution | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Single-arm | | Parallel groups | | Crossover | | Other or n/a | |
| **Allocation** | **Control** | **Masking** | **N** | **%col** | **n** | **%row** | **n** | **%row** | **n** | **%row** | **n** | **%row** |
| Randomised controlled | Active | Open | 9 | 31.0 | | | 7 | 77.8 | | | 2 | 22.2 |
| | | Double-blind | 2 | 6.9 | 1 | 50.0 | | | 1 | 50.0 | | |
| | | Single-blind | 6 | 20.7 | | | 5 | 83.3 | | | 1 | 16.7 |
| | Placebo | Double-blind | 4 | 13.8 | | | 4 | 100.0 | | | | |
| | | Single-blind | 2 | 6.9 | | | 2 | 100.0 | | | | |
| | Before/after | Double-blind | 1 | 3.4 | 1 | 100.0 | | | | | | |
| | None | Open | 3 | 10.3 | | | 2 | 66.7 | 1 | 33.3 | | |
| | | Double-blind | 1 | 3.4 | 1 | 100.0 | | | | | | |
| | | Single-blind | 1 | 3.4 | | | 1 | 100.0 | | | | |
| | | All | 29 | 100.0 | 3 | 10.3 | 21 | 72.4 | 2 | 6.9 | 3 | 10.3 |
| Non-random. controlled | Active | Open | 1 | 14.3 | | | | | | | 1 | 100.0 |
| | Before/after | Open | 2 | 28.6 | | | 1 | 50.0 | | | 1 | 50.0 |
| | None | Open | 4 | 57.1 | 3 | 75.0 | | | | | 1 | 25.0 |
| | | All | 7 | 100.0 | 3 | 42.9 | 1 | 14.3 | | | 3 | 42.9 |
| Not applicable | Active | Open | 1 | 3.6 | 1 | 100.0 | | | | | | |
| | | Single-blind | 3 | 10.7 | | | | | 2 | 66.7 | 1 | 33.3 |
| | Before/after | Open | 1 | 3.6 | | | | | | | 1 | 100.0 |
| | | Single-blind | 1 | 3.6 | 1 | 100.0 | | | | | | |
| | Dosage | Open | 1 | 3.6 | | | | | | | 1 | 100.0 |
| | None | Open | 19 | 67.9 | 10 | 52.6 | 1 | 5.3 | | | 8 | 42.1 |
| | | Single-blind | 2 | 7.1 | 2 | 100.0 | | | | | | |
| | | All | 28 | 100.0 | 14 | 50.0 | 1 | 3.6 | 2 | 7.1 | 11 | 39.3 |
| Total number | | | 64 | 100.0 | 20 | 31.2 | 23 | 35.9 | 4 | 6.2 | 17 | 26.6 |

**Table 25:** Stratification of **medical device trials** by information on standard use of medical devices with conformity marking and details for non-standard use as well as whether first in man.

| | | | | | CE-marked + standard use | | | | Details of medical device | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Yes | | No | | Not CE-marked | | CE but non-intended use | | First in man | |
| Allocation | Control | Masking | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Randomised controlled | Active | Open | 9 | 31.0 | 9 | 100.0 | | | | | | | | |
| | | Double-blind | 2 | 6.9 | 2 | 100.0 | | | | | | | 1 | 50.0 |
| | | Single-blind | 6 | 20.7 | 5 | 83.3 | 1 | 16.7 | 1 | 100.0 | | | | |
| | Placebo | Double-blind | 4 | 13.8 | 3 | 75.0 | 1 | 25.0 | | | 1 | 100.0 | | |
| | | Single-blind | 2 | 6.9 | 2 | 100.0 | | | | | | | | |
| | Before/after | Double-blind | 1 | 3.4 | 1 | 100.0 | | | | | | | | |
| | None | Open | 3 | 10.3 | 2 | 66.7 | 1 | 33.3 | 1 | 100.0 | | | 1 | 33.3 |
| | | Double-blind | 1 | 3.4 | 1 | 100.0 | | | | | | | | |
| | | Single-blind | 1 | 3.4 | 1 | 100.0 | | | | | | | | |
| | | All | 29 | 100.0 | 26 | 89.7 | 3 | 10.3 | 2 | 66.7 | 1 | 33.3 | 2 | 6.9 |
| Non-random. controlled | Active | Open | 1 | 14.3 | 1 | 100.0 | | | | | | | | |
| | Before/after | Open | 2 | 28.6 | 2 | 100.0 | | | | | | | | |
| | None | Open | 4 | 57.1 | 1 | 25.0 | 3 | 75.0 | 3 | 100.0 | | | 2 | 50.0 |
| | | All | 7 | 100.0 | 4 | 57.1 | 3 | 42.9 | 3 | 100.0 | | | 2 | 28.6 |
| Not applicable | Active | Open | 1 | 3.6 | 1 | 100.0 | | | | | | | | |
| | | Single-blind | 3 | 10.7 | 3 | 100.0 | | | | | | | | |
| | Before/after | Open | 1 | 3.6 | 1 | 100.0 | | | | | | | | |
| | | Single-blind | 1 | 3.6 | 1 | 100.0 | | | | | | | | |
| | Dosage | Open | 1 | 3.6 | 1 | 100.0 | | | | | | | | |
| | None | Open | 19 | 67.9 | 12 | 63.2 | 6 | 31.6 | 6 | 100.0 | | | 4 | 21.1 |
| | | Single-blind | 2 | 7.1 | 2 | 100.0 | | | | | | | | |
| | | All | 28 | 100.0 | 21 | 75.0 | 6 | 21.4 | 6 | 100.0 | | | 4 | 14.3 |
| Total number | | | 64 | 100.0 | 51 | 79.7 | 12 | 18.8 | 11 | 91.7 | 1 | 8.3 | 8 | 12.5 |

Note: 1 of 51 medical device trials with 'standard use' are risk category 'C' the rest is 'A', explaining potential discrepancies to Table 11.

### 4.4.2.3 Subgroup "Other clinical trials" (ClinO Art 61)

**Table 26:** Stratification of **other clinical trials** by risk category, study design and initiator of the research project. The classification of clinical trials according to allocation, control and masking technique is BASEC-specific.

| | | | | | Risk category | | | | Study design | | | | | | Initiator | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | A | | B | | Mono | | Multi CH | | Multi Int. | | Industry | | Investigator | |
| Allocation | Control | Masking | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Randomised controlled | Active | Open | 21 | 25.9 | 17 | 81.0 | 4 | 19.0 | 11 | 52.4 | 1 | 4.8 | 9 | 42.9 | 2 | 9.5 | 19 | 90.5 |
| | | Double-blind | 2 | 2.5 | 1 | 50.0 | 1 | 50.0 | 1 | 50.0 | | | 1 | 50.0 | | | 2 | 100.0 |
| | | Single-blind | 17 | 21.0 | 16 | 94.1 | 1 | 5.9 | 11 | 64.7 | 4 | 23.5 | 2 | 11.8 | 1 | 5.9 | 16 | 94.1 |
| | Placebo | Open | 1 | 1.2 | | | 1 | 100.0 | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | Double-blind | 11 | 13.6 | 9 | 81.8 | 2 | 18.2 | 9 | 81.8 | 2 | 18.2 | | | 1 | 9.1 | 10 | 90.9 |
| | | Single-blind | 2 | 2.5 | 2 | 100.0 | | | 2 | 100.0 | | | | | | | 2 | 100.0 |
| | Before/after | Open | 3 | 3.7 | 3 | 100.0 | | | 2 | 66.7 | | | 1 | 33.3 | 1 | 33.3 | 2 | 66.7 |
| | | Double-blind | 1 | 1.2 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | Single-blind | 4 | 4.9 | 4 | 100.0 | | | 4 | 100.0 | | | | | | | 4 | 100.0 |
| | Dosage | Open | 1 | 1.2 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | Double-blind | 1 | 1.2 | 1 | 100.0 | | | 1 | 100.0 | | | | | 1 | 100.0 | | |
| | | Single-blind | 2 | 2.5 | 2 | 100.0 | | | 2 | 100.0 | | | | | | | 2 | 100.0 |
| | None | Open | 12 | 14.8 | 12 | 100.0 | | | 6 | 50.0 | 3 | 25.0 | 3 | 25.0 | | | 12 | 100.0 |
| | | Double-blind | 1 | 1.2 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | Single-blind | 2 | 2.5 | 2 | 100.0 | | | 2 | 100.0 | | | | | | | 2 | 100.0 |
| | | All | 81 | 100.0 | 72 | 88.9 | 9 | 11.1 | 55 | 67.9 | 10 | 12.3 | 16 | 19.8 | 6 | 7.4 | 75 | 92.6 |
| Non-random. controlled | Active | Open | 4 | 44.4 | 4 | 100.0 | | | 3 | 75.0 | | | 1 | 25.0 | | | 4 | 100.0 |
| | | Single-blind | 1 | 11.1 | 1 | 100.0 | | | | | 1 | 100.0 | | | | | 1 | 100.0 |
| | None | Open | 4 | 44.4 | 3 | 75.0 | 1 | 25.0 | 4 | 100.0 | | | | | | | 4 | 100.0 |
| | | All | 9 | 100.0 | 8 | 88.9 | 1 | 11.1 | 7 | 77.8 | 1 | 11.1 | 1 | 11.1 | | | 9 | 100.0 |
| Not applicable | Active | Open | 1 | 4.0 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | Placebo | Open | 1 | 4.0 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | Before/after | Open | 3 | 12.0 | 3 | 100.0 | | | 3 | 100.0 | | | | | | | 3 | 100.0 |
| | | Single-blind | 1 | 4.0 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | None | Open | 18 | 72.0 | 17 | 94.4 | 1 | 5.6 | 15 | 83.3 | | | 3 | 16.7 | 4 | 22.2 | 14 | 77.8 |
| | | Single-blind | 1 | 4.0 | 1 | 100.0 | | | 1 | 100.0 | | | | | | | 1 | 100.0 |
| | | All | 25 | 100.0 | 24 | 96.0 | 1 | 4.0 | 22 | 88.0 | | | 3 | 12.0 | 4 | 16.0 | 21 | 84.0 |
| Total number | | | 115 | 100.0 | 104 | 90.4 | 11 | 9.6 | 84 | 73.0 | 11 | 9.6 | 20 | 17.4 | 10 | 8.7 | 105 | 91.3 |

**Table 27:** Stratification of **other clinical trials** by participant arms/distribution.

| | | | | | Participant arms/distribution | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Single-arm | | Parallel groups | | Crossover | | Factorial | | Other or n/a | |
| Allocation | Control | Masking | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Randomised controlled | Active | Open | 21 | 25.9 | | | 17 | 81.0 | 3 | 14.3 | | | 1 | 4.8 |
| | | Double-blind | 2 | 2.5 | | | 2 | 100.0 | | | | | | |
| | | Single-blind | 17 | 21.0 | | | 15 | 88.2 | 2 | 11.8 | | | | |
| | Placebo | Open | 1 | 1.2 | | | | | 1 | 100.0 | | | | |
| | | Double-blind | 11 | 13.6 | 1 | 9.1 | 5 | 45.5 | 5 | 45.5 | | | | |
| | | Single-blind | 2 | 2.5 | | | 1 | 50.0 | 1 | 50.0 | | | | |
| | Before/after | Open | 3 | 3.7 | | | 3 | 100.0 | | | | | | |
| | | Double-blind | 1 | 1.2 | | | 1 | 100.0 | | | | | | |
| | | Single-blind | 4 | 4.9 | | | 4 | 100.0 | | | | | | |
| | Dosage | Open | 1 | 1.2 | | | 1 | 100.0 | | | | | | |
| | | Double-blind | 1 | 1.2 | | | 1 | 100.0 | | | | | | |
| | | Single-blind | 2 | 2.5 | | | 1 | 50.0 | 1 | 50.0 | | | | |
| | None | Open | 12 | 14.8 | 1 | 8.3 | 5 | 41.7 | 4 | 33.3 | | | 2 | 16.7 |
| | | Double-blind | 1 | 1.2 | | | 1 | 100.0 | | | | | | |
| | | Single-blind | 2 | 2.5 | | | 2 | 100.0 | | | | | | |
| | | All | 81 | 100.0 | 2 | 2.5 | 59 | 72.8 | 17 | 21.0 | | | 3 | 3.7 |
| Non-random. controlled | Active | Open | 4 | 44.4 | | | 2 | 50.0 | | | | | 2 | 50.0 |
| | | Single-blind | 1 | 11.1 | | | | | 1 | 100.0 | | | | |
| | None | Open | 4 | 44.4 | 1 | 25.0 | 1 | 25.0 | 1 | 25.0 | | | 1 | 25.0 |
| | | All | 9 | 100.0 | 1 | 11.1 | 3 | 33.3 | 2 | 22.2 | | | 3 | 33.3 |
| Not applicable | Active | Open | 1 | 4.0 | | | | | | | | | 1 | 100.0 |
| | Placebo | Open | 1 | 4.0 | | | | | | | 1 | 100.0 | | |
| | Before/after | Open | 3 | 12.0 | 1 | 33.3 | | | 1 | 33.3 | | | 1 | 33.3 |
| | | Single-blind | 1 | 4.0 | | | | | 1 | 100.0 | | | | |
| | None | Open | 18 | 72.0 | 10 | 55.6 | | | 2 | 11.1 | | | 6 | 33.3 |
| | | Single-blind | 1 | 4.0 | 1 | 100.0 | | | | | | | | |
| | | All | 25 | 100.0 | 12 | 48.0 | | | 4 | 16.0 | 1 | 4.0 | 8 | 32.0 |
| Total number | | | 115 | 100.0 | 15 | 13.0 | 62 | 53.9 | 23 | 20.0 | 1 | 0.9 | 14 | 12.2 |

### 4.4.3 Subgroup "Research involving persons, but not a clinical trial" - research covered by HRO Chapter 2

**Table 28:** Stratification of **research projects involving persons, but not a clinical trial,** by risk category, study design and initiator. The 'type of research projects' reported in the following tables are self-reported and BASEC-specific without a legal basis in the HRA.

| | | | Risk category | | | | Study design | | | | | | Initiator | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | A | | B | | Mono | | Multi CH | | Multi Int. | | Industry | | Investigator | |
| Type of research project | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Cohort study | 46 | 9.7 | 43 | 93.5 | 3 | 6.5 | 35 | 76.1 | 3 | 6.5 | 8 | 17.4 | | | 46 | 100.0 |
| Registry / Quality control [1] | 18 | 3.8 | 17 | 94.4 | 1 | 5.6 | 8 | 44.4 | | | 10 | 55.6 | 4 | 22.2 | 14 | 77.8 |
| Case control study | 29 | 6.1 | 29 | 100.0 | | | 26 | 89.7 | | | 3 | 10.3 | | | 29 | 100.0 |
| Other or n/a [2] | 380 | 80.3 | 372 | 97.9 | 8 | 2.1 | 282 | 74.2 | 33 | 8.7 | 65 | 17.1 | 36 | 9.5 | 344 | 90.5 |
| | 473 | 100.0 | 461 | 97.5 | 12 | 2.5 | 351 | 74.2 | 36 | 7.6 | 86 | 18.2 | 40 | 8.5 | 433 | 91.5 |

[1] Only quality control studies under the HRA.
[2] This group also includes projects declared as 'observational study' before this option was disabled on August 21, 2017.

**Table 29:** Stratification of **research projects involving persons, but not a clinical trial,** by whether the research project was solely or principally designed to obtain a degree - and if yes, what degree.

| | | | | | What degree (multiple answers possible) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | Primarily for degree | | MD/PhD thesis | | Master | | Other degree | |
| Type of research project | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Cohort study | 46 | 9.7 | 13 | 28.3 | 10 | 76.9 | 3 | 23.1 | | |
| Registry / Quality control | 18 | 3.8 | 3 | 16.7 | 1 | 33.3 | 2 | 66.7 | | |
| Case control study | 29 | 6.1 | 12 | 41.4 | 5 | 41.7 | 7 | 58.3 | | |
| Other or n/a | 380 | 80.3 | 172 | 45.3 | 80 | 46.5 | 90 | 52.3 | 8 | 4.7 |
| | 473 | 100.0 | 200 | 42.3 | 96 | 48.0 | 102 | 51.0 | 8 | 4.0 |

**Table 30:** Stratification of **research projects involving persons, but not a clinical trial,** by ethics committee.

| | | | Ethics committee | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | KEK-ZH | | EKNZ | | CER-VD | | KEK-BE | | CCER | | EKOS | | CE-TI | |
| **Type of research project** | **N** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** |
| Cohort study | 46 | 9.7 | 11 | 12.1 | 9 | 8.4 | 6 | 5.3 | 5 | 7.2 | 10 | 17.2 | 4 | 18.2 | 1 | 8.3 |
| Registry / Quality control | 18 | 3.8 | 7 | 7.7 | 5 | 4.7 | 2 | 1.8 | 1 | 1.4 | 2 | 3.4 | 1 | 4.5 | | |
| Case control study | 29 | 6.1 | 9 | 9.9 | 7 | 6.5 | 5 | 4.4 | 2 | 2.9 | 4 | 6.9 | 1 | 4.5 | 1 | 8.3 |
| Other or n/a | 380 | 80.3 | 64 | 70.3 | 86 | 80.4 | 101 | 88.6 | 61 | 88.4 | 42 | 72.4 | 16 | 72.7 | 10 | 83.3 |
| | 473 | 100.0 | 91 | 100.0 | 107 | 100.0 | 114 | 100.0 | 69 | 100.0 | 58 | 100.0 | 22 | 100.0 | 12 | 100.0 |

**Table 31:** Stratification of **research projects involving persons, but not a clinical trial,** by review procedure and first decision.

| | | | Review procedure | | | | | | First decision | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | Ordinary | | Simplified | | Presidential | | Approved | | Charges | | Conditions | | Declined | | Non-consid. | |
| Type of research project | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Cohort study | 46 | 9.7 | 5 | 10.9 | 38 | 82.6 | 3 | 6.5 | 4 | 8.7 | 17 | 37.0 | 25 | 54.3 | | | | |
| Registry / Quality control | 18 | 3.8 | 2 | 11.1 | 15 | 83.3 | 1 | 5.6 | 1 | 5.6 | 7 | 38.9 | 10 | 55.6 | | | | |
| Case control study | 29 | 6.1 | 1 | 3.4 | 27 | 93.1 | 1 | 3.4 | | | 11 | 37.9 | 18 | 62.1 | | | | |
| Other or n/a | 380 | 80.3 | 28 | 7.4 | 345 | 90.8 | 7 | 1.8 | 28 | 7.4 | 154 | 40.5 | 196 | 51.6 | 1 | 0.3 | 1 | 0.3 |
| | 473 | 100.0 | 36 | 7.6 | 425 | 89.9 | 12 | 2.5 | 33 | 7.0 | 189 | 40.0 | 249 | 52.6 | 1 | 0.2 | 1 | 0.2 |

CE-TI reviews all projects in an 'Ordinary procedure'.

### 4.4.4 Subgroup "Further use of data/biological material" - research covered by HRO Chapter 3

**Table 32:** Overview of characteristics of all approved 'further use' projects.

| | | n | % |
|---|---|---|---|
| Genetic data / biol. material | Yes | 76 | 13.38 |
| | No | 490 | 86.27 |
| Coding (HRO Art. 25-27) | Coded | 240 | 42.25 |
| | Open, non-coded | 326 | 57.39 |
| Consent (HRO Art. 28-32) | Prior consent exists | 115 | 20.25 |
| | Consent to be sought [1] | 56 | 9.86 |
| | No consent for some/all data (HRA Art 34) | 395 | 69.54 |
| Combined projects [2] | Further use project | 566 | 99.65 |
| | Part of clinical trial | 2 | 0.35 |
| | Part of non-clinical research project | 0 | 0.00 |
| | Total number | 568 | 100.00 |

[1] Consent to be sought means that the ECs do not apply HRA Art 34 and request the researchers to obtain the consent

[2] For research projects concerning a clinical trial (ClinO) or research involving persons according to HRO Chapter 2, there is the possibility to simultaneously apply in BASEC for the 'further use' of existing data or biological material (HRO Chapter 3).

#### 4.4.4.1 Description and derivation of stratification variables applied to "further use" projects

The projects are stratified based on the following 3 questions:

**Genetic data:** The BASEC question "Your project involves" can be answered with "Non-genetic data only" or "Genetic-data and/or biological material".

**Coding:** The BASEC question "Please select how your research data will be kept" can be answered with "Coded" or "Open, non-coded". A reference to HRO Art. 25-27 is provided.

**Consent:** The BASEC question "Consent for further use of data/material" can be answered with "Prior consent exists", "Consent to be sought" or "No consent for some or all of the samples/data". Applicants are informed that if they "Have an informed consent from before the human research act (2014), check whether it is conformable to law (Articles 28-32 HRO). If not, the consent is not sufficient. If there is pre-existing consent for some samples/records, but not for others, Art 34 HRA may apply".

A "Further use" project nested into a clinical trial or a HRO research project involving persons requires an additional justification statement to be provided: "Justification and information for the use of Art. 34 HRA", "Confirmation that no data/samples will be used, if a document refusal exists" and "Justification of interest of research".

**Table 33:** Stratification of **projects involving further use of data/biological material** by study design and initiator. All combinations of the following three factors are shown: 1) Use of genetic data and/or biological material (Genetic D+M), 2) coded vs. uncoded, 3) consent for further use. Approved applications for which Art. 34 HRA has been requested are listed separately at the bottom (total of all projects with 'No consent for some/all data').

| | | | | | Study design | | | | | | Initiator | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Mono | | Multi CH | | Multi Int. | | Industry | | Investigator | |
| Genetic D+M | Coded | Consent | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Yes | Coded | Prior consent exists | 23 | 46.9 | 14 | 60.9 | 1 | 4.3 | 8 | 34.8 | 10 | 43.5 | 13 | 56.5 |
| | | Consent to be sought | 5 | 10.2 | 2 | 40.0 | 1 | 20.0 | 2 | 40.0 | 2 | 40.0 | 3 | 60.0 |
| | | No consent for some/all data (HRA Art 34) | 21 | 42.9 | 13 | 61.9 | 2 | 9.5 | 6 | 28.6 | 1 | 4.8 | 20 | 95.2 |
| | | All | 49 | 100.0 | 29 | 59.2 | 4 | 8.2 | 16 | 32.7 | 13 | 26.5 | 36 | 73.5 |
| | Open, non-coded | Prior consent exists | 3 | 11.1 | 3 | 100.0 | | | | | | | 3 | 100.0 |
| | | Consent to be sought | 3 | 11.1 | 2 | 66.7 | | | 1 | 33.3 | | | 3 | 100.0 |
| | | No consent for some/all data (HRA Art 34) | 21 | 77.8 | 18 | 85.7 | | | 3 | 14.3 | 2 | 9.5 | 19 | 90.5 |
| | | All | 27 | 100.0 | 23 | 85.2 | | | 4 | 14.8 | 2 | 7.4 | 25 | 92.6 |
| | All | | 76 | 100.0 | 52 | 68.4 | 4 | 5.3 | 20 | 26.3 | 15 | 19.7 | 61 | 80.3 |
| No | Coded | Prior consent exists | 44 | 23.0 | 35 | 79.5 | 2 | 4.5 | 7 | 15.9 | 4 | 9.1 | 40 | 90.9 |
| | | Consent to be sought | 27 | 14.1 | 19 | 70.4 | 1 | 3.7 | 7 | 25.9 | 4 | 14.8 | 23 | 85.2 |
| | | No consent for some/all data (HRA Art 34) | 120 | 62.8 | 104 | 86.7 | 9 | 7.5 | 7 | 5.8 | 1 | 0.8 | 119 | 99.2 |
| | | All | 191 | 100.0 | 158 | 82.7 | 12 | 6.3 | 21 | 11.0 | 9 | 4.7 | 182 | 95.3 |
| | Open, non-coded | Prior consent exists | 45 | 15.1 | 41 | 91.1 | 2 | 4.4 | 2 | 4.4 | | | 45 | 100.0 |
| | | Consent to be sought | 21 | 7.0 | 21 | 100.0 | | | | | | | 21 | 100.0 |
| | | No consent for some/all data (HRA Art 34) | 233 | 77.9 | 212 | 91.0 | 13 | 5.6 | 8 | 3.4 | | | 233 | 100.0 |
| | | All | 299 | 100.0 | 274 | 91.6 | 15 | 5.0 | 10 | 3.3 | | | 299 | 100.0 |
| | All | | 490 | 100.0 | 432 | 88.2 | 27 | 5.5 | 31 | 6.3 | 9 | 1.8 | 481 | 98.2 |
| | | Total HRA Art 34 | 395 | 100.0 | 347 | 87.8 | 24 | 6.1 | 24 | 6.1 | 4 | 1.0 | 391 | 99.0 |
| Total number | | | 568 | 100.0 | 486 | 85.6 | 31 | 5.5 | 51 | 9.0 | 24 | 4.2 | 544 | 95.8 |

The total number of 568 research projects consist of 566 standard 'further use' projects and 2 ClinO or research with persons (HRO) projects that include further use of data/biological material.

**Table 34:** Stratification of **projects involving further use of data/biological material. All combinations of the following three factors are shown: 1) Use of genetic data and/or biological material (Genetic D+M), 2) coded vs. uncoded, 3) consent for further use. Approved applications for which Art. 34 HRA has been requested are listed separately at the bottom (total of all projects with 'No consent for some/all data')** by whether the research project was solely or principally designed to obtain a degree - and if yes, what degree.

| | | | | | | | What degree (multiple answers possible) | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Primarily for degree | | MD/PhD thesis | | Master | | Other degree | |
| Genetic D+M | Coded | Consent | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Yes | Coded | Prior consent exists | 23 | 46.9 | 2 | 8.7 | 2 | 100.0 | | | | |
| | | Consent to be sought | 5 | 10.2 | | | | | | | | |
| | | No consent for some/all data (HRA Art 34) | 21 | 42.9 | 8 | 38.1 | 2 | 25.0 | 5 | 62.5 | 1 | 12.5 |
| | | All | 49 | 100.0 | 10 | 20.4 | 4 | 40.0 | 5 | 50.0 | 1 | 10.0 |
| | Open, non-coded | Prior consent exists | 3 | 11.1 | 1 | 33.3 | 1 | 100.0 | | | | |
| | | Consent to be sought | 3 | 11.1 | 2 | 66.7 | 2 | 100.0 | | | | |
| | | No consent for some/all data (HRA Art 34) | 21 | 77.8 | 5 | 23.8 | | | 5 | 100.0 | | |
| | | All | 27 | 100.0 | 8 | 29.6 | 3 | 37.5 | 5 | 62.5 | | |
| | All | | 76 | 100.0 | 18 | 23.7 | 7 | 38.9 | 10 | 55.6 | 1 | 5.6 |
| No | Coded | Prior consent exists | 44 | 23.0 | 21 | 47.7 | 10 | 47.6 | 12 | 57.1 | | |
| | | Consent to be sought | 27 | 14.1 | 6 | 22.2 | 2 | 33.3 | 4 | 66.7 | | |
| | | No consent for some/all data (HRA Art 34) | 120 | 62.8 | 69 | 57.5 | 38 | 55.1 | 30 | 43.5 | 3 | 4.3 |
| | | All | 191 | 100.0 | 96 | 50.3 | 50 | 52.1 | 46 | 47.9 | 3 | 3.1 |
| | Open, non-coded | Prior consent exists | 45 | 15.1 | 24 | 53.3 | 6 | 25.0 | 17 | 70.8 | 2 | 8.3 |
| | | Consent to be sought | 21 | 7.0 | 11 | 52.4 | 4 | 36.4 | 5 | 45.5 | 2 | 18.2 |
| | | No consent for some/all data (HRA Art 34) | 233 | 77.9 | 128 | 54.9 | 61 | 47.7 | 67 | 52.3 | 6 | 4.7 |
| | | All | 299 | 100.0 | 163 | 54.5 | 71 | 43.6 | 89 | 54.6 | 10 | 6.1 |
| | All | | 490 | 100.0 | 259 | 52.9 | 121 | 46.7 | 135 | 52.1 | 13 | 5.0 |
| | | Total HRA Art 34 | 395 | 100.0 | 210 | 53.2 | 101 | 48.1 | 107 | 51.0 | 10 | 4.8 |
| Total number | | | 568 | 100.0 | 279 | 49.1 | 128 | 45.9 | 145 | 52.0 | 16 | 5.7 |

**Table 35:** Stratification of **projects involving further use of data/biological material** by ethics committee.

| | | | Ethics committee | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Total | | KEK-ZH | | EKNZ | | CER-VD | | KEK-BE | | CCER | | EKOS | | CE-TI | |
| **Consent** | **N** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** | **n** | **%col** |
| Prior consent exists | 115 | 20.2 | 35 | 20.0 | 28 | 23.9 | 19 | 17.4 | 16 | 17.6 | 12 | 26.7 | 2 | 10.0 | 3 | 27.3 |
| Consent to be sought | 56 | 9.9 | 22 | 12.6 | 14 | 12.0 | 3 | 2.8 | 5 | 5.5 | 5 | 11.1 | 2 | 10.0 | 5 | 45.5 |
| No consent for some/all data (HRA Art 34) | 395 | 69.5 | 118 | 67.4 | 75 | 64.1 | 87 | 79.8 | 70 | 76.9 | 28 | 62.2 | 14 | 70.0 | 3 | 27.3 |
| | 568 | 100.0 | 175 | 100.0 | 117 | 100.0 | 109 | 100.0 | 91 | 100.0 | 45 | 100.0 | 20 | 100.0 | 11 | 100.0 |

Note that there are regional differences in time point of the introduction of the 'general consent' and some hospitals have not introduced it yet.

**Table 36:** Stratification of **projects involving further use of data/biological material. All combinations of the following three factors are shown: 1) Use of genetic data and/or biological material (Genetic D+M), 2) coded vs. uncoded, 3) consent for further use. Approved applications for which Art. 34 HRA has been requested are listed separately at the bottom (total of all projects with 'No consent for some/all data')** by review procedure and first decision.

| | | | | | Review procedure | | | | | | First decision | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Total | | Ordinary | | Simplified | | Presidential | | Approved | | Charges | | Conditions | | Declined | |
| Genetic D+M | Coded | Consent | N | $\%_{col}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ | n | $\%_{row}$ |
| Yes | Coded | Prior consent exists | 23 | 46.9 | | | 7 | 30.4 | 16 | 69.6 | 12 | 52.2 | 8 | 34.8 | 3 | 13.0 | | |
| | | Consent to be sought | 5 | 10.2 | 2 | 40.0 | | | 3 | 60.0 | 1 | 20.0 | 2 | 40.0 | 2 | 40.0 | | |
| | | No consent for some/all data (HRA Art 34) | 21 | 42.9 | 1 | 4.8 | 19 | 90.5 | 1 | 4.8 | 6 | 28.6 | 10 | 47.6 | 5 | 23.8 | | |
| | | All | 49 | 100.0 | 3 | 6.1 | 26 | 53.1 | 20 | 40.8 | 19 | 38.8 | 20 | 40.8 | 10 | 20.4 | | |
| | Open, non-coded | Prior consent exists | 3 | 11.1 | 1 | 33.3 | | | 2 | 66.7 | 2 | 66.7 | | | 1 | 33.3 | | |
| | | Consent to be sought | 3 | 11.1 | 1 | 33.3 | 1 | 33.3 | 1 | 33.3 | | | 2 | 66.7 | 1 | 33.3 | | |
| | | No consent for some/all data (HRA Art 34) | 21 | 77.8 | 1 | 4.8 | 19 | 90.5 | 1 | 4.8 | 7 | 33.3 | 5 | 23.8 | 9 | 42.9 | | |
| | | All | 27 | 100.0 | 3 | 11.1 | 20 | 74.1 | 4 | 14.8 | 9 | 33.3 | 7 | 25.9 | 11 | 40.7 | | |
| | All | | 76 | 100.0 | 6 | 7.9 | 46 | 60.5 | 24 | 31.6 | 28 | 36.8 | 27 | 35.5 | 21 | 27.6 | | |
| No | Coded | Prior consent exists | 44 | 23.0 | | | 21 | 47.7 | 23 | 52.3 | 17 | 38.6 | 8 | 18.2 | 19 | 43.2 | | |
| | | Consent to be sought | 27 | 14.1 | 2 | 7.4 | 14 | 51.9 | 11 | 40.7 | 7 | 25.9 | 6 | 22.2 | 14 | 51.9 | | |
| | | No consent for some/all data (HRA Art 34) | 120 | 62.8 | 2 | 1.7 | 115 | 95.8 | 3 | 2.5 | 33 | 27.5 | 44 | 36.7 | 42 | 35.0 | 1 | 0.8 |
| | | All | 191 | 100.0 | 4 | 2.1 | 150 | 78.5 | 37 | 19.4 | 57 | 29.8 | 58 | 30.4 | 75 | 39.3 | 1 | 0.5 |
| | Open, non-coded | Prior consent exists | 45 | 15.1 | 2 | 4.4 | 13 | 28.9 | 30 | 66.7 | 20 | 44.4 | 13 | 28.9 | 12 | 26.7 | | |
| | | Consent to be sought | 21 | 7.0 | 2 | 9.5 | 6 | 28.6 | 13 | 61.9 | 1 | 4.8 | 6 | 28.6 | 14 | 66.7 | | |
| | | No consent for some/all data (HRA Art 34) | 233 | 77.9 | 1 | 0.4 | 227 | 97.4 | 5 | 2.1 | 66 | 28.3 | 85 | 36.5 | 82 | 35.2 | | |
| | | All | 299 | 100.0 | 5 | 1.7 | 246 | 82.3 | 48 | 16.1 | 87 | 29.1 | 104 | 34.8 | 108 | 36.1 | | |
| | All | | 490 | 100.0 | 9 | 1.8 | 396 | 80.8 | 85 | 17.3 | 144 | 29.4 | 162 | 33.1 | 183 | 37.3 | 1 | 0.2 |
| | | Total HRA Art 34 | 395 | 100.0 | 5 | 1.3 | 380 | 96.2 | 10 | 2.5 | 112 | 28.4 | 144 | 36.5 | 138 | 34.9 | 1 | 0.3 |
| Total number | | | 568 | 100.0 | 15 | 2.6 | 443 | 78.0 | 110 | 19.4 | 174 | 30.6 | 189 | 33.3 | 204 | 35.9 | 1 | 0.2 |

CE-TI reviews all projects in an 'Ordinary procedure'.

## 4.5 Information about the parties involved in human research projects

### 4.5.1 Project initiator and funding

**Description of distinctive features of the results:**

Table 37 shows that investigator-initiated studies are mostly publicly funded and even when the funding comes from industry, a PI from academia is the initiator. Conversely, industry-initiated studies tend to be (purely) industry-funded and if not, mostly an industry sponsor is involved. This table indicates that the question "Who initiated the project?" is a good proxy for distinguishing between industry-driven projects and investigator-initiated studies.

**Table 37:** Answers to the question "Who initiated the project?" stratified by the main financing source.

| Initiator | Financing (main source) | n | $\%_{col}$ |
|---|---|---|---|
| Investigator | Public, other | 753 | 65.9 |
| | Industry | 49 [1] | 4.3 |
| | Universities/hospitals | 184 | 16.1 |
| | Private (non-industry) | 70 | 6.1 |
| | SNF | 87 | 7.6 |
| | All | 1143 | 100.0 |
| Industry | Public, other | 41 [2] | 21.7 |
| | Industry | 145 [3] | 76.7 |
| | Universities/hospitals | 2 | 1.1 |
| | Private (non-industry) | 1 | 0.5 |
| | SNF | 0 | 0.0 |
| | All | 189 | 100.0 |
| Other | Public, other | 39 | 79.6 |
| | Industry | 2 | 4.1 |
| | Universities/hospitals | 2 | 4.1 |
| | Private (non-industry) | 6 | 12.2 |
| | SNF | 0 | 0.0 |
| | All | 49 [4] | 100.0 |

[1] Applicants almost exclusively from academic institutions.
[2] Inspecting the sponsor information reveals that these are almost exclusively industry projects.
[3] 144 of the industry-initiated projects are financed exclusively by industry.
[4] 26 of these projects initiated by others are projects solely or principally designed to obtain a degree (the tutor is the initiator). Apart from that, these projects are quite heterogenous.

### 4.5.2 Applicant of the project

**Table 38:** Overview of the applicants of the project.

| Applicant | Type of research | n | $\%_{col}$ |
|---|---|---|---|
| Project leader / PI [1] | Clinical trial | 186 | 16.0 |
| | Research w/ persons | 420 | 36.2 |
| | Further use | 536 | 46.2 |
| | Deceased, embryos | 17 | 1.5 |
| | Total | 1159 | 100.0 |
| Sponsor | Clinical trial | 58 | 55.2 |
| | Research w/ persons | 33 | 31.4 |
| | Further use | 14 | 13.3 |
| | Deceased, embryos | 0 | 0.0 |
| | Total | 105 | 100.0 |
| CRO | Clinical trial | 47 | 72.3 |
| | Research w/ persons | 10 | 15.4 |
| | Further use | 8 | 12.3 |
| | Deceased, embryos | 0 | 0.0 |
| | Total | 65 | 100.0 |
| Sponsor's representative in CH | Clinical trial | 33 | 63.5 |
| | Research w/ persons | 10 | 19.2 |
| | Further use | 8 | 15.4 |
| | Deceased, embryos | 1 | 1.9 |
| | Total | 52 | 100.0 |
| Overall | Clinical trial | 324 | 23.5 |
| | Research w/ persons | 473 | 34.3 |
| | Further use | 566 | 41.0 |
| | Deceased, embryos | 18 | 1.3 |
| | Total | 1381 | 100.0 |

[1] 'Project leader' includes sponsor responsibility

# 5 Response times and review procedure (AS2)

## 5.1 Definitions

As described in the introduction on page 7, the data analysed in the following are self-reported by the individual ECs. As outlined in Figure 8, the ECs manually enter the dates of milestones for all individual applications into BASEC. Thereby the only two periods that solely depend on the EC are: 1) reception (initial submission) to first reaction and 2) application data complete to first decision. The interval between "first reaction" and "application complete" is mainly dependent on the applicant. All other intervals encompass periods in the responsibility of both EC and applicant. During any request of information by the EC directed to the applicant, a clock-stop of the EC deadline may be applied, but clock-stops are not consistently tracked in BASEC.

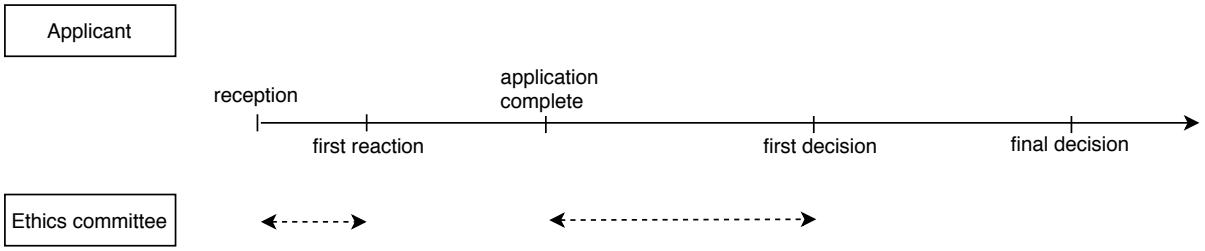


**Figure 8:** Overview of dates of milestones reported by the ECs for each application. The only two periods that purely depend on the EC are denoted.

## 5.2 Overview of median response times

**Description of distinctive features of the results:**

By inspecting Table 39 next page, differences in response times and type of procedures between EK become apparent. These are primarily explained by their different modes of operation and by how response times and status changes are reported but potentially also by regional differences in the type of submitted research projects.

**Table 39:** Overview of response times in days - median (M) and inter-quartile range (IQR) per review procedure and ethics committee.

| | | | | Time interval from ... | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | receipt to first reply | | receipt to complete | | receipt to first decision | | receipt to final decision | | complete to first d. | | complete to final d. | |
| Procedure | EC | N | $\%_{EC}$ | Median | IQR | Median | IQR | Median | IQR | Median | IQR | Median | IQR | Median | IQR |
| Ordinary | KEK-ZH | 40 | 11 | 7 | [ 7, 11] | 35 | [ 24, 41] | 50 | [ 42, 59 ] | 98 | [ 85, 150 ] | 16 | [ 13, 21] | 64 | [ 48, 117] |
| | EKNZ | 60 | 19 | 5 | [ 3, 7] | 5 | [ 3, 8] | 34 | [ 27, 44 ] | 90 | [ 58, 120 ] | 28 | [ 20, 38] | 83 | [ 54, 114] |
| | CER-VD | 34 | 13 | 6 | [ 3, 7] | 6 | [ 3, 7] | 30 | [ 26, 35 ] | 84 | [ 65, 114 ] | 26 | [ 22, 30] | 80 | [ 57, 110] |
| | KEK-BE | 26 | 13 | 4 | [ 1, 5] | 5 | [ 1, 6] | 31 | [ 24, 46 ] | 127 | [ 87, 152 ] | 26 | [ 20, 36] | 120 | [ 84, 141] |
| | CCER | 7 | 5 | 5 | [ 0, 9] | 8 | [ 1, 9] | 41 | [ 27, 60 ] | 104 | [ 84, 128 ] | 33 | [ 26, 50] | 103 | [ 84, 115] |
| | EKOS | 11 | 17 | 5 | [ 2, 6] | 5 | [ 2, 6] | 29 | [ 26, 43 ] | 84 | [ 70, 98 ] | 28 | [ 22, 38] | 83 | [ 68, 94] |
| | CE-TI | 47 | 100 | 7 | [ 7, 7] | 7 | [ 7, 8] | 36 | [ 23, 38 ] | 53 | [ 30, 90 ] | 28 | [ 16, 31] | 44 | [ 26, 79] |
| | All | 225 | 16 | 6 | [ 3, 7] | 7 | [ 4, 10] | 36 | [ 27, 47 ] | 87 | [ 59, 126 ] | 25 | [ 16, 32] | 77 | [ 48, 116] |
| Simplified | KEK-ZH | 255 | 73 | 7 | [ 7, 10] | 38 | [ 28, 60] | 53 | [ 41, 76 ] | 79 | [ 50, 114 ] | 13 | [ 10, 16] | 30 | [ 16, 52] |
| | EKNZ | 237 | 74 | 5 | [ 2, 7] | 5 | [ 2, 7] | 24 | [ 19, 29 ] | 51 | [ 32, 67 ] | 18 | [ 14, 23] | 43 | [ 28, 59] |
| | CER-VD | 210 | 79 | 5 | [ 3, 6] | 5 | [ 3, 7] | 27 | [ 22, 32 ] | 64 | [ 52, 82 ] | 21 | [ 17, 25] | 59 | [ 49, 77] |
| | KEK-BE | 178 | 86 | 3 | [ 1, 5] | 4 | [ 1, 7] | 21 | [ 18, 27 ] | 54 | [ 28, 79 ] | 16 | [ 15, 20] | 50 | [ 22, 70] |
| | CCER | 112 | 88 | 3 | [ 1, 6] | 6 | [ 2, 8] | 30 | [ 23, 37 ] | 69 | [ 58, 104 ] | 24 | [ 20, 30] | 65 | [ 50, 94] |
| | EKOS | 41 | 64 | 2 | [ 1, 4] | 2 | [ 1, 4] | 18 | [ 13, 25 ] | 30 | [ 17, 56 ] | 15 | [ 10, 22] | 28 | [ 15, 54] |
| | CE-TI | 0 | 0 | | [ , ] | | [ , ] | | [ , ] | | [ , ] | | [ , ] | | [ , ] |
| | All | 1033 | 75 | 5 | [ 2, 7] | 6 | [ 3, 22] | 27 | [ 21, 41 ] | 62 | [ 43, 90 ] | 16 | [ 14, 22] | 48 | [ 27, 68] |
| Presidential | KEK-ZH | 53 | 15 | 7 | [ 7, 8] | 45 | [ 35, 64] | 50 | [ 41, 69 ] | 68 | [ 48, 90 ] | 4 | [ 1, 6] | 11 | [ 7, 26] |
| | EKNZ | 25 | 8 | 4 | [ 1, 8] | 4 | [ 1, 10] | 14 | [ 9, 24 ] | 26 | [ 14, 64 ] | 8 | [ 6, 13] | 20 | [ 9, 38] |
| | CER-VD | 22 | 8 | 5 | [ 3, 7] | 6 | [ 3, 9] | 22 | [ 16, 40 ] | 28 | [ 17, 53 ] | 16 | [ 9, 21] | 17 | [ 10, 23] |
| | KEK-BE | 2 | 1 | 4 | [ 4, 4] | 8 | [ 6, 9] | 32 | [ 26, 37 ] | 50 | [ 35, 66 ] | 24 | [ 20, 28] | 43 | [ 29, 57] |
| | CCER | 9 | 7 | 4 | [ 3, 6] | 4 | [ 3, 6] | 9 | [ 6, 11 ] | 9 | [ 6, 11 ] | 4 | [ 4, 7] | 4 | [ 4, 7] |
| | EKOS | 12 | 19 | 4 | [ 3, 4] | 4 | [ 3, 4] | 18 | [ 12, 25 ] | 20 | [ 12, 88 ] | 14 | [ 8, 21] | 18 | [ 8, 84] |
| | CE-TI | 0 | 0 | | [ , ] | | [ , ] | | [ , ] | | [ , ] | | [ , ] | | [ , ] |
| | All | 123 | 9 | 6 | [ 3, 7] | 10 | [ 4, 44] | 30 | [ 14, 48 ] | 45 | [ 20, 82 ] | 7 | [ 4, 14] | 15 | [ 7, 30] |
| Overall | KEK-ZH | 348 | 100 | 7 | [ 7, 9] | 38 | [ 29, 57] | 52 | [ 41, 73 ] | 82 | [ 54, 113 ] | 12 | [ 8, 16] | 30 | [ 15, 55] |
| | EKNZ | 322 | 100 | 5 | [ 2, 7] | 5 | [ 2, 8] | 25 | [ 19, 33 ] | 54 | [ 34, 82 ] | 19 | [ 13, 26] | 48 | [ 28, 70] |
| | CER-VD | 266 | 100 | 5 | [ 3, 6] | 5 | [ 3, 7] | 27 | [ 22, 32 ] | 64 | [ 51, 87 ] | 21 | [ 16, 26] | 59 | [ 44, 78] |
| | KEK-BE | 206 | 100 | 3 | [ 1, 5] | 4 | [ 1, 7] | 21 | [ 18, 28 ] | 57 | [ 32, 90 ] | 16 | [ 15, 21] | 51 | [ 23, 84] |
| | CCER | 128 | 100 | 3 | [ 1, 6] | 6 | [ 2, 8] | 29 | [ 22, 37 ] | 69 | [ 55, 104 ] | 22 | [ 19, 30] | 64 | [ 48, 94] |
| | EKOS | 64 | 100 | 3 | [ 2, 4] | 3 | [ 2, 4] | 20 | [ 14, 27 ] | 34 | [ 19, 82 ] | 18 | [ 11, 24] | 32 | [ 16, 78] |
| | CE-TI | 47 | 100 | 7 | [ 7, 7] | 7 | [ 7, 8] | 36 | [ 23, 38 ] | 53 | [ 30, 90 ] | 28 | [ 16, 31] | 44 | [ 26, 79] |
| | All | 1381 | 100 | 6 | [ 3, 7] | 6 | [ 3, 24] | 29 | [ 21, 43 ] | 64 | [ 43, 94 ] | 17 | [ 13, 24] | 49 | [ 25, 74] |

CE-TI reviews all projects in an 'Ordinary procedure'.

## 5.3 Stratification of response time by review procedure

### 5.3.1 Time from status “complete” to first decision

**Definition:**

In the following, **violin plots** are used to visualise the distribution of response times. Violin plots are similar to box plots except that they show more details on the distribution of the data by showing the probability density of the data at different values (kernel density plot). In addition, we denote the 1st, 2nd and 3rd quartile of the data by vertical lines in the plot which makes the data comparable to what is provided in the tables (median and inter-quartile range).

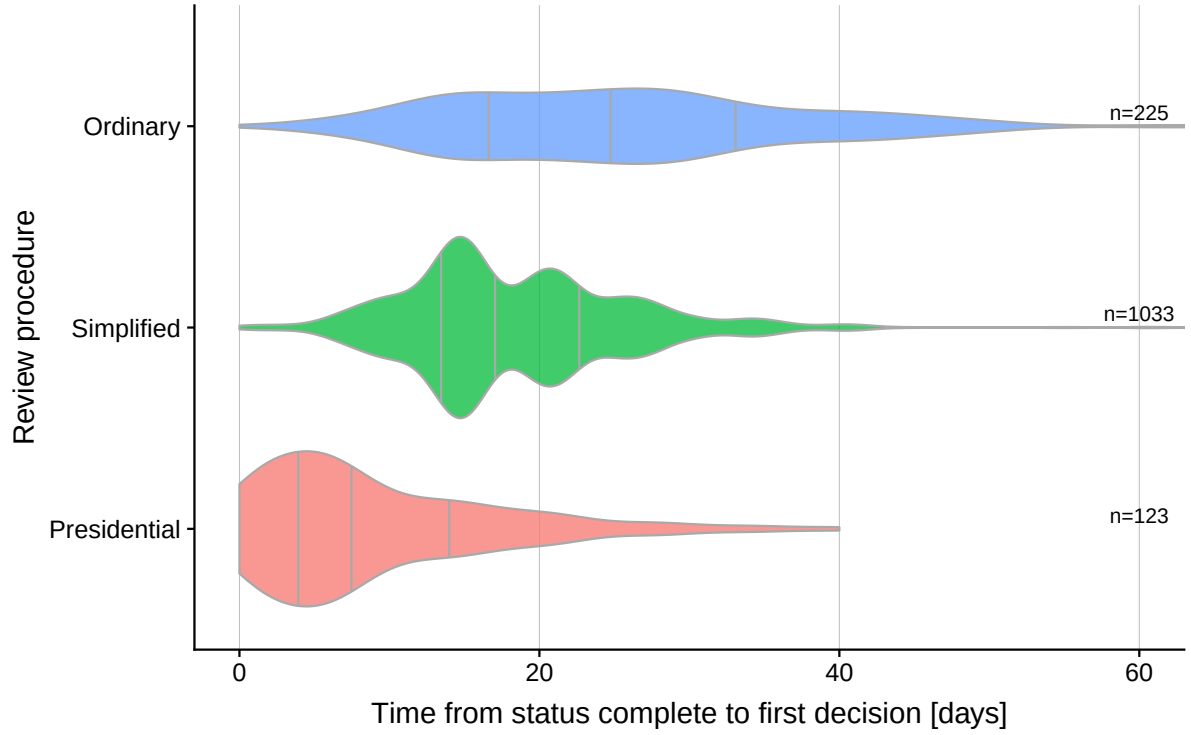


**Figure 9:** Violin plot (kernel density plot) of the time between status ’complete’ to the first decision (i.e. the time between submission is considered ’complete’ to final decision) by review procedure. 11 projects with t > 60 days are not shown for layout reasons.

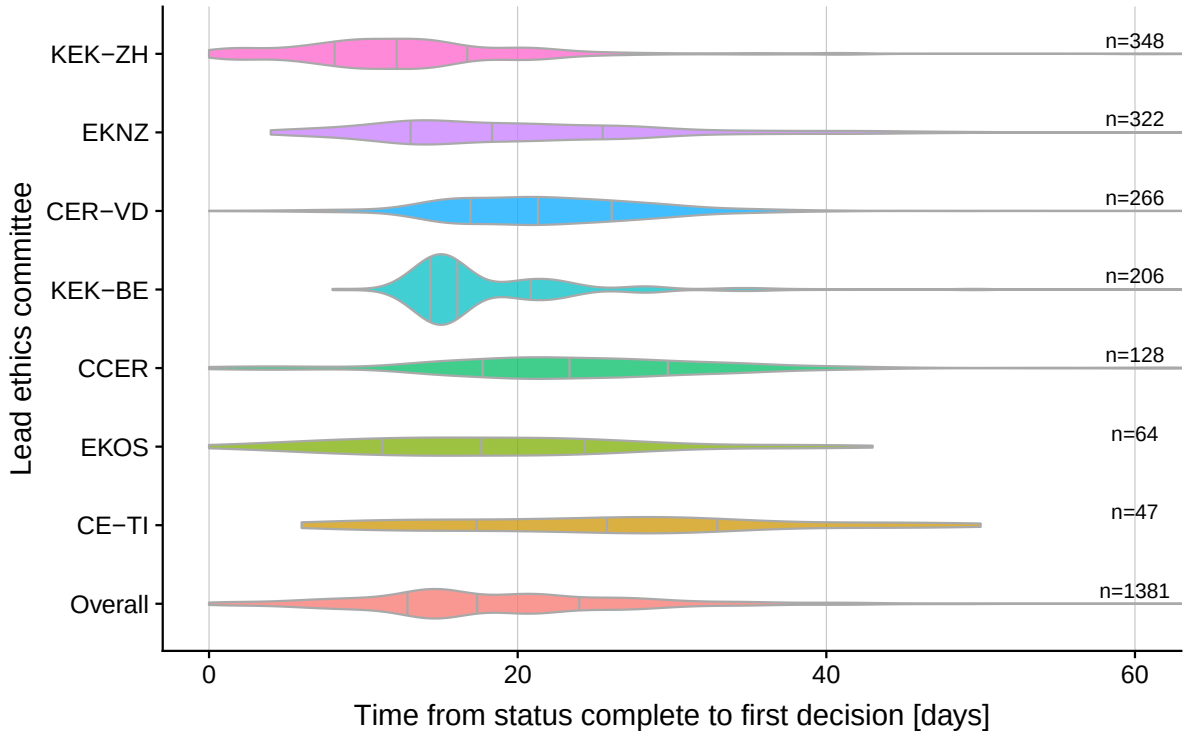


**Figure 10:** Violin plot of the time between status 'complete' to the first decision by EC. 11 projects with t > 60 days are not shown for layout reasons for layout reasons.

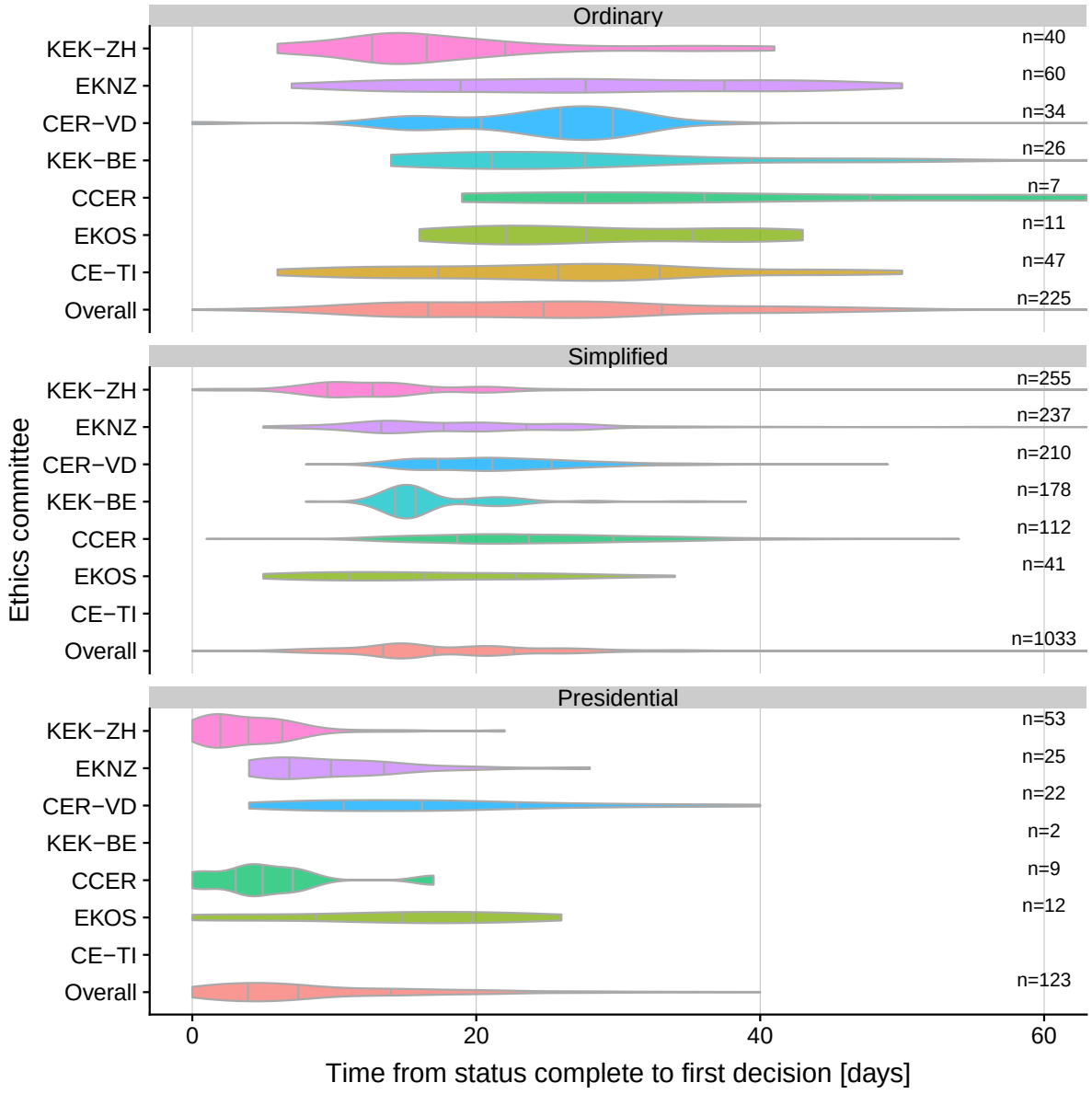


**Figure 11:** Violin plot of the time between status 'complete' to the first decision by EC and stratified by review procedure. 11 projects with t > 60 days are not shown for layout reasons. Note: *CE-TI* typically processes all submissions in a plenary session (ordinary procedure) but with adapted fees.

### 5.3.2 Time from status “complete” to final decision

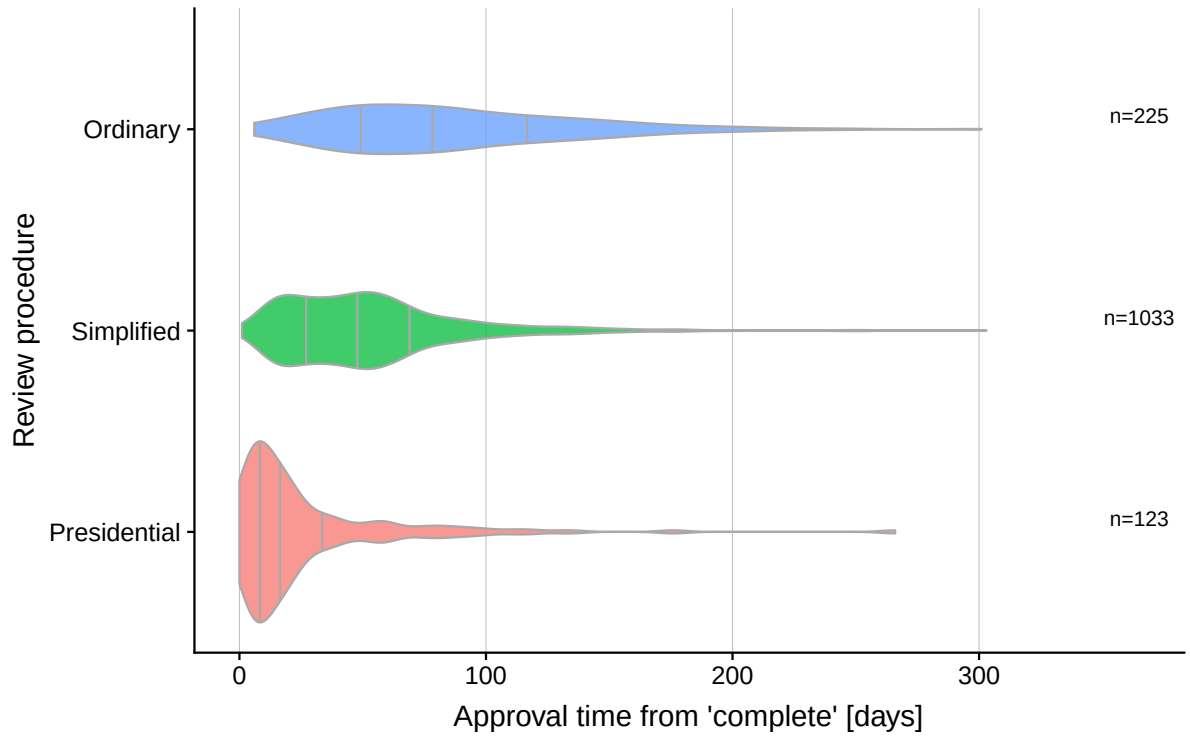


**Figure 12:** Violin plot of the approval time (i.e. the time between submission is considered ‘complete’ to final decision) by review procedure. 0 projects with approval time > 1 year are not shown for layout reasons.

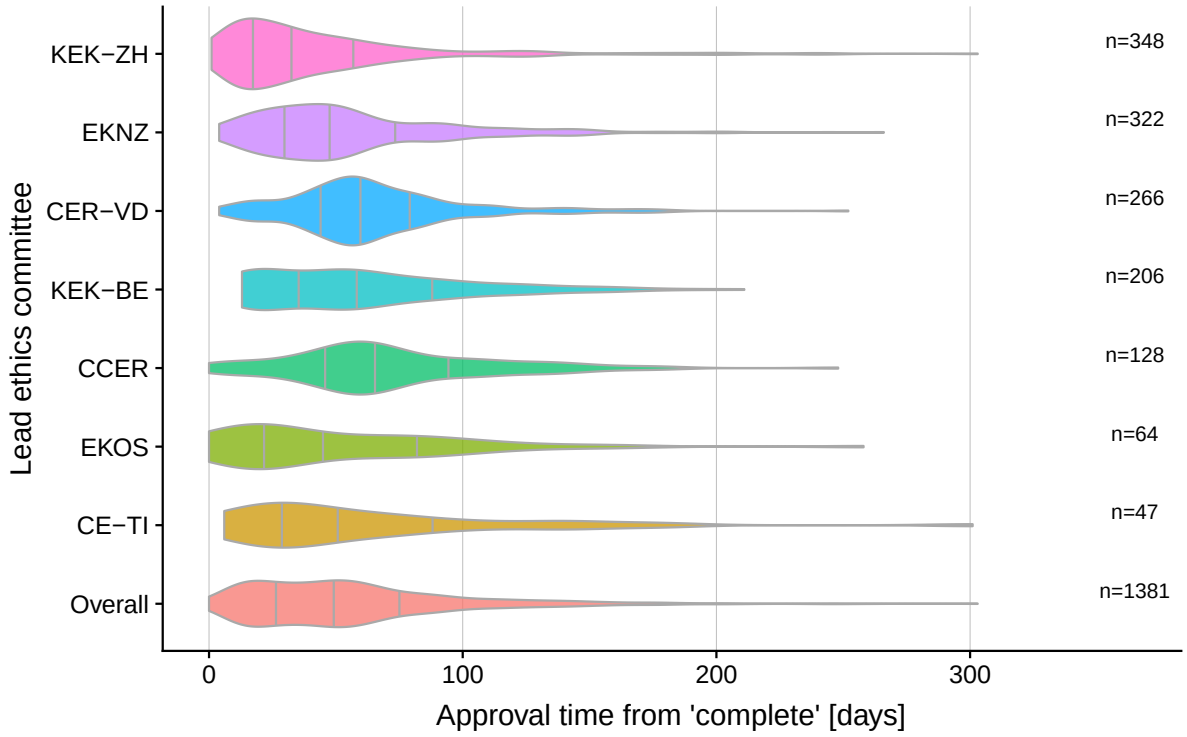


**Figure 13:** Violin plot of the approval time by EC. 0 projects with approval time > 1 year are not shown for layout reasons.

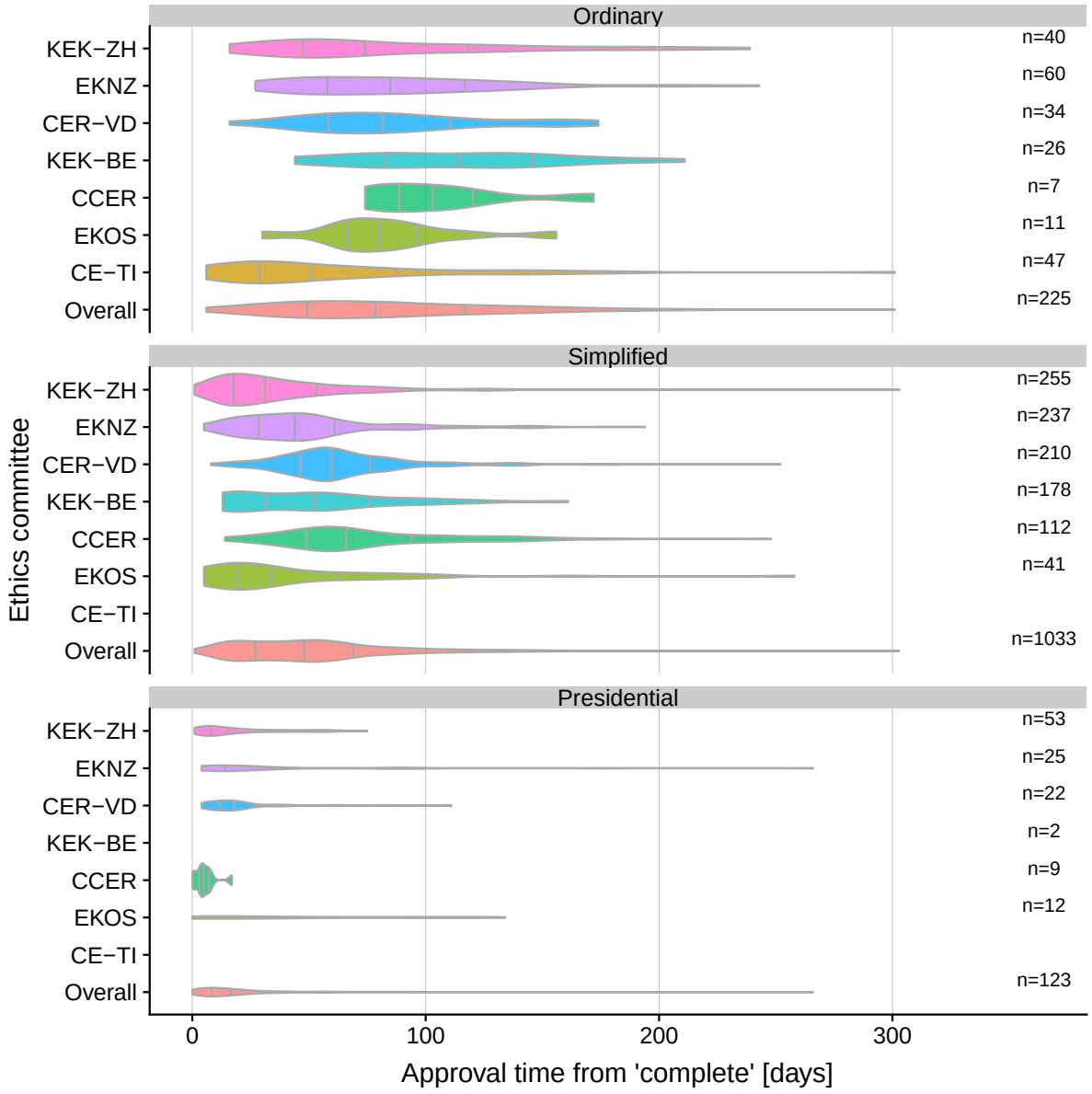


**Figure 14:** Violin plot of the approval time by EC and stratified by review procedure. 0 projects with approval time > 1 year are not shown for layout reasons.

### 5.3.3 Time from reception to final decision

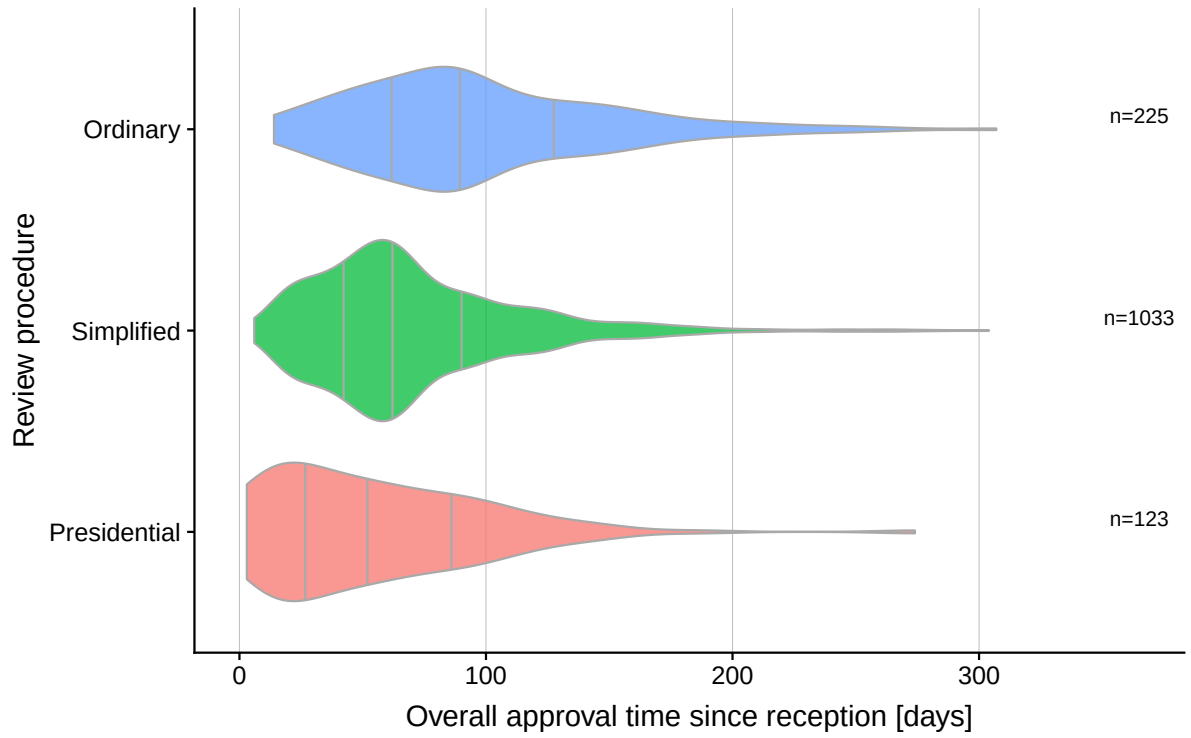


**Figure 15:** Violin plot of the overall approval time (i.e. the time between reception to final decision) by review procedure. 0 projects with approval time > 1 year are not shown for layout reasons.

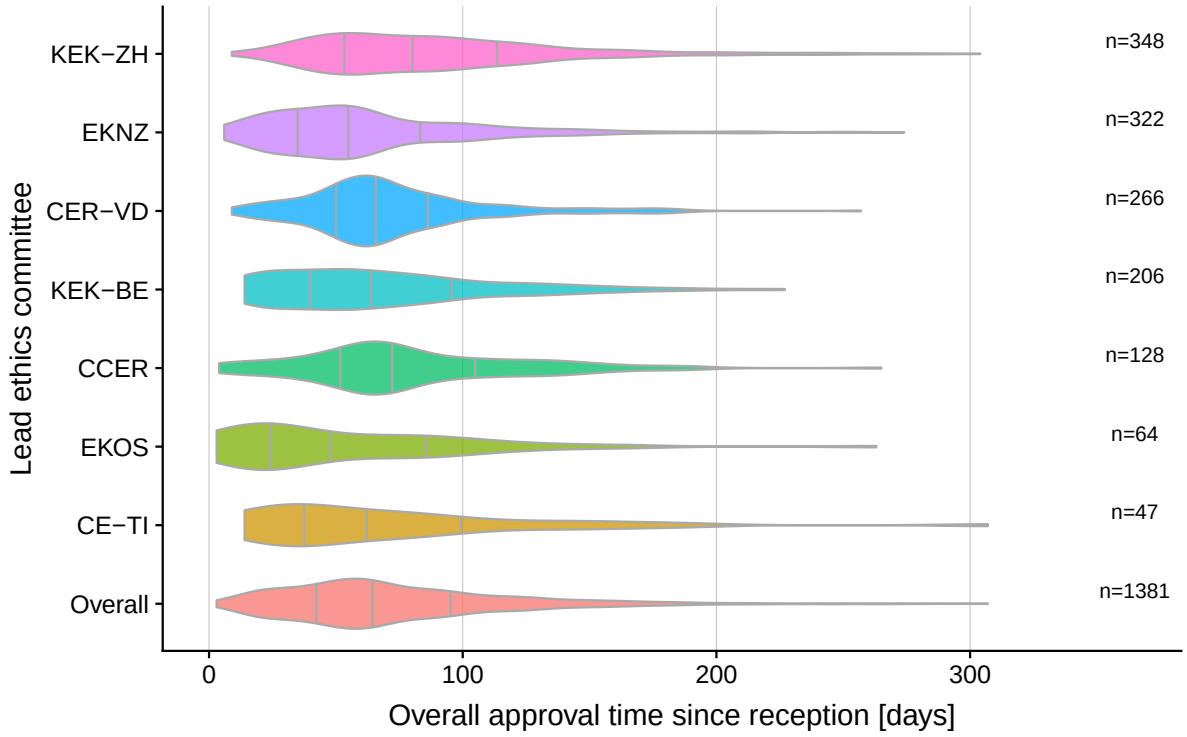


**Figure 16:** Violin plot of the overall approval time by EC. 0 projects with approval time > 1 year are not shown for layout reasons.

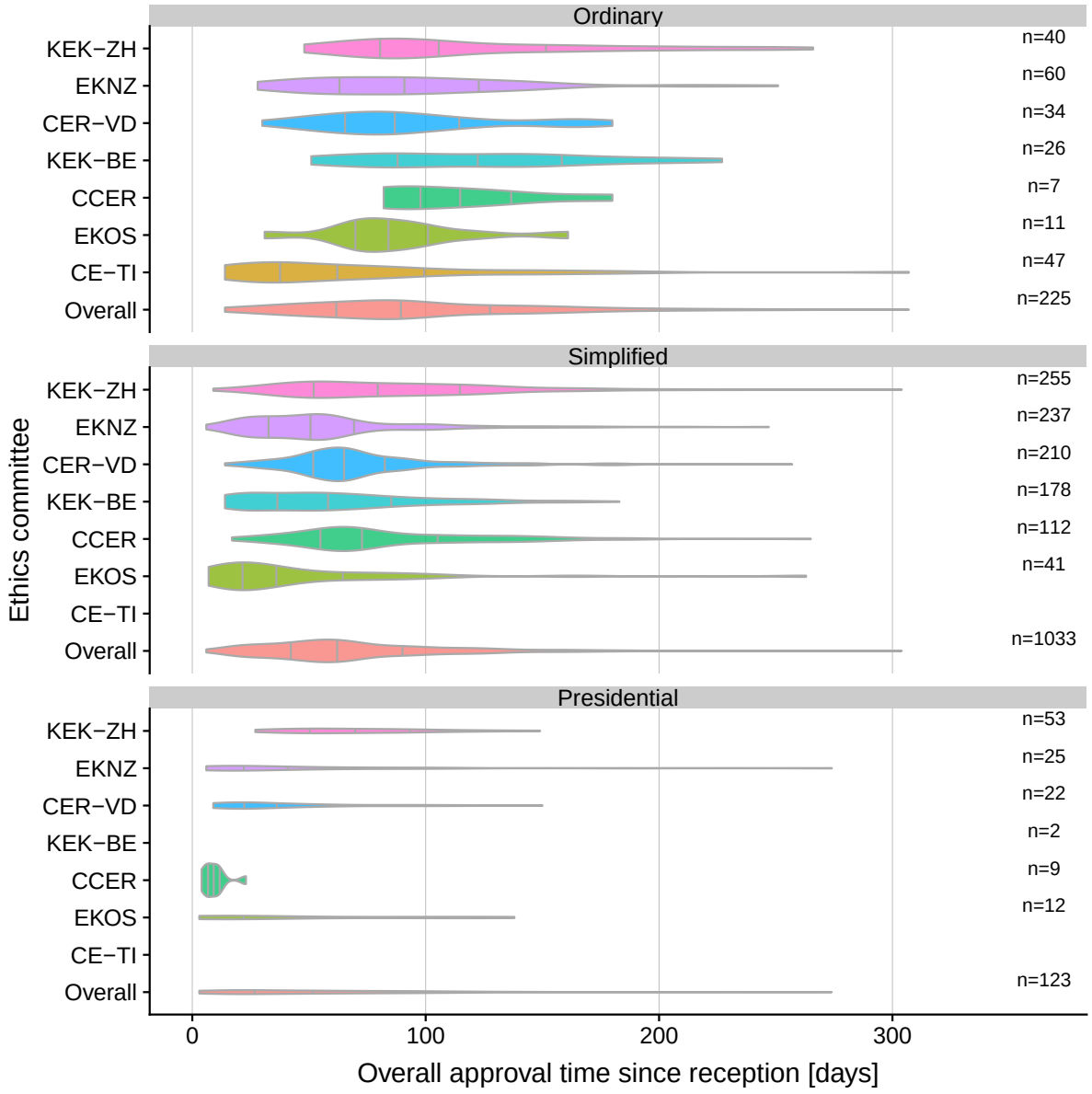


**Figure 17:** Violin plot of the overall approval time by EC and stratified by review procedure. 0 projects with approval time > 1 year are not shown for layout reasons.

## 5.4 Stratification of response time by type of research

**Table 40:** Overview of response time in days - Median (M) and inter-quartile range (IQR) per type of research (3 major groups only) and ethics committee.

| | | | | Time interval from ... | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | receipt to first reply | | receipt to complete | | receipt to first decision | | receipt to final decision | | complete to first d. | | complete to final d. | |
| Type of research | EC | N | $\%_{EC}$ | Median | IQR | Median | IQR | Median | IQR | Median | IQR | Median | IQR | Median | IQR |
| Clinical trial | KEK-ZH | 79 | 23 | 7 | [ 7, 10] | 41 | [ 34, 69] | 59 | [ 48, 84 ] | 103 | [ 86, 132 ] | 15 | [ 12, 20] | 50 | [ 36, 80] |
| | EKNZ | 91 | 29 | 5 | [ 4, 8] | 5 | [ 3, 8] | 32 | [ 21, 43 ] | 78 | [ 54, 109 ] | 22 | [ 15, 33] | 71 | [ 49, 98] |
| | CER-VD | 41 | 16 | 5 | [ 3, 6] | 5 | [ 3, 7] | 28 | [ 25, 34 ] | 78 | [ 63, 97 ] | 25 | [ 19, 30] | 72 | [ 56, 96] |
| | KEK-BE | 46 | 22 | 4 | [ 1, 5] | 5 | [ 2, 7] | 28 | [ 20, 40 ] | 98 | [ 82, 132 ] | 20 | [ 16, 28] | 92 | [ 72, 120] |
| | CCER | 20 | 16 | 2 | [ 1, 7] | 7 | [ 2, 10] | 36 | [ 26, 41 ] | 86 | [ 75, 127 ] | 26 | [ 20, 34] | 84 | [ 66, 108] |
| | EKOS | 23 | 36 | 3 | [ 2, 5] | 3 | [ 2, 5] | 25 | [ 22, 28 ] | 70 | [ 30, 88 ] | 22 | [ 18, 27] | 66 | [ 29, 84] |
| | CE-TI | 24 | 51 | 7 | [ 7, 7] | 7 | [ 7, 7] | 30 | [ 20, 37 ] | 61 | [ 27, 104 ] | 22 | [ 13, 30] | 52 | [ 21, 98] |
| | All | 324 | 24 | 6 | [ 3, 7] | 7 | [ 4, 24] | 34 | [ 25, 48 ] | 88 | [ 63, 118 ] | 20 | [ 15, 28] | 70 | [ 46, 99] |
| Research w/ persons | KEK-ZH | 91 | 26 | 7 | [ 7, 11] | 48 | [ 36, 79] | 63 | [ 52, 94 ] | 99 | [ 70, 128 ] | 14 | [ 10, 16] | 34 | [ 21, 56] |
| | EKNZ | 107 | 34 | 5 | [ 2, 7] | 5 | [ 2, 8] | 24 | [ 19, 29 ] | 56 | [ 42, 67 ] | 19 | [ 14, 23] | 48 | [ 36, 58] |
| | CER-VD | 114 | 43 | 5 | [ 3, 6] | 5 | [ 3, 7] | 27 | [ 23, 34 ] | 68 | [ 56, 89 ] | 22 | [ 17, 27] | 63 | [ 50, 81] |
| | KEK-BE | 69 | 33 | 4 | [ 1, 5] | 4 | [ 2, 7] | 21 | [ 19, 27 ] | 61 | [ 45, 90 ] | 16 | [ 14, 20] | 50 | [ 29, 83] |
| | CCER | 58 | 47 | 3 | [ 1, 7] | 5 | [ 2, 8] | 30 | [ 24, 38 ] | 69 | [ 60, 106 ] | 25 | [ 20, 27] | 67 | [ 55, 96] |
| | EKOS | 22 | 34 | 4 | [ 2, 4] | 4 | [ 2, 4] | 18 | [ 14, 27 ] | 38 | [ 28, 83 ] | 16 | [ 12, 22] | 33 | [ 26, 79] |
| | CE-TI | 12 | 26 | 8 | [ 7, 8] | 8 | [ 7, 8] | 36 | [ 33, 42 ] | 46 | [ 37, 68 ] | 28 | [ 23, 34] | 39 | [ 28, 52] |
| | All | 473 | 35 | 5 | [ 2, 7] | 6 | [ 3, 17] | 28 | [ 21, 43 ] | 67 | [ 51, 99 ] | 19 | [ 14, 25] | 54 | [ 35, 72] |
| Further use | KEK-ZH | 174 | 51 | 7 | [ 7, 9] | 34 | [ 24, 46] | 44 | [ 35, 57 ] | 57 | [ 43, 83 ] | 10 | [ 5, 13] | 19 | [ 9, 36] |
| | EKNZ | 117 | 37 | 4 | [ 1, 7] | 4 | [ 1, 7] | 21 | [ 15, 27 ] | 34 | [ 21, 55 ] | 14 | [ 12, 22] | 27 | [ 18, 48] |
| | CER-VD | 109 | 41 | 4 | [ 3, 6] | 5 | [ 3, 7] | 26 | [ 22, 31 ] | 58 | [ 40, 73 ] | 20 | [ 16, 24] | 52 | [ 25, 66] |
| | KEK-BE | 91 | 44 | 2 | [ 1, 5] | 4 | [ 1, 6] | 21 | [ 17, 26 ] | 42 | [ 22, 62 ] | 15 | [ 15, 20] | 35 | [ 16, 58] |
| | CCER | 45 | 37 | 3 | [ 1, 6] | 5 | [ 3, 7] | 26 | [ 19, 35 ] | 63 | [ 31, 79 ] | 21 | [ 15, 28] | 53 | [ 21, 75] |
| | EKOS | 19 | 30 | 2 | [ 2, 4] | 2 | [ 2, 4] | 16 | [ 8, 20 ] | 17 | [ 9, 24 ] | 12 | [ 6, 17] | 15 | [ 6, 23] |
| | CE-TI | 11 | 23 | 7 | [ 6, 7] | 7 | [ 7, 8] | 36 | [ 30, 44 ] | 57 | [ 38, 90 ] | 28 | [ 22, 32] | 47 | [ 30, 74] |
| | All | 566 | 42 | 6 | [ 2, 7] | 7 | [ 3, 26] | 27 | [ 20, 41 ] | 50 | [ 28, 72 ] | 15 | [ 10, 21] | 29 | [ 15, 56] |
| Overall | KEK-ZH | 344 | 100 | 7 | [ 7, 9] | 38 | [ 29, 56] | 52 | [ 41, 72 ] | 82 | [ 54, 114 ] | 12 | [ 8, 16] | 30 | [ 15, 55] |
| | EKNZ | 315 | 100 | 5 | [ 2, 7] | 5 | [ 2, 8] | 25 | [ 19, 33 ] | 54 | [ 34, 82 ] | 19 | [ 13, 26] | 48 | [ 28, 72] |
| | CER-VD | 264 | 100 | 5 | [ 3, 6] | 5 | [ 3, 7] | 27 | [ 22, 32 ] | 64 | [ 51, 87 ] | 21 | [ 17, 26] | 59 | [ 44, 78] |
| | KEK-BE | 206 | 100 | 3 | [ 1, 5] | 4 | [ 1, 7] | 21 | [ 18, 28 ] | 57 | [ 32, 90 ] | 16 | [ 15, 21] | 51 | [ 23, 84] |
| | CCER | 123 | 100 | 3 | [ 1, 6] | 5 | [ 2, 8] | 29 | [ 22, 38 ] | 69 | [ 56, 104 ] | 22 | [ 18, 30] | 65 | [ 48, 96] |
| | EKOS | 64 | 100 | 3 | [ 2, 4] | 3 | [ 2, 4] | 20 | [ 14, 27 ] | 34 | [ 19, 82 ] | 18 | [ 11, 24] | 32 | [ 16, 78] |
| | CE-TI | 47 | 100 | 7 | [ 7, 7] | 7 | [ 7, 8] | 36 | [ 23, 38 ] | 53 | [ 30, 90 ] | 28 | [ 16, 31] | 44 | [ 26, 79] |
| | All | 1363 | 100 | 6 | [ 3, 7] | 6 | [ 3, 24] | 29 | [ 21, 43 ] | 64 | [ 43, 94 ] | 17 | [ 13, 24] | 49 | [ 25, 75] |

### 5.4.1 Time from status “complete” to final decision

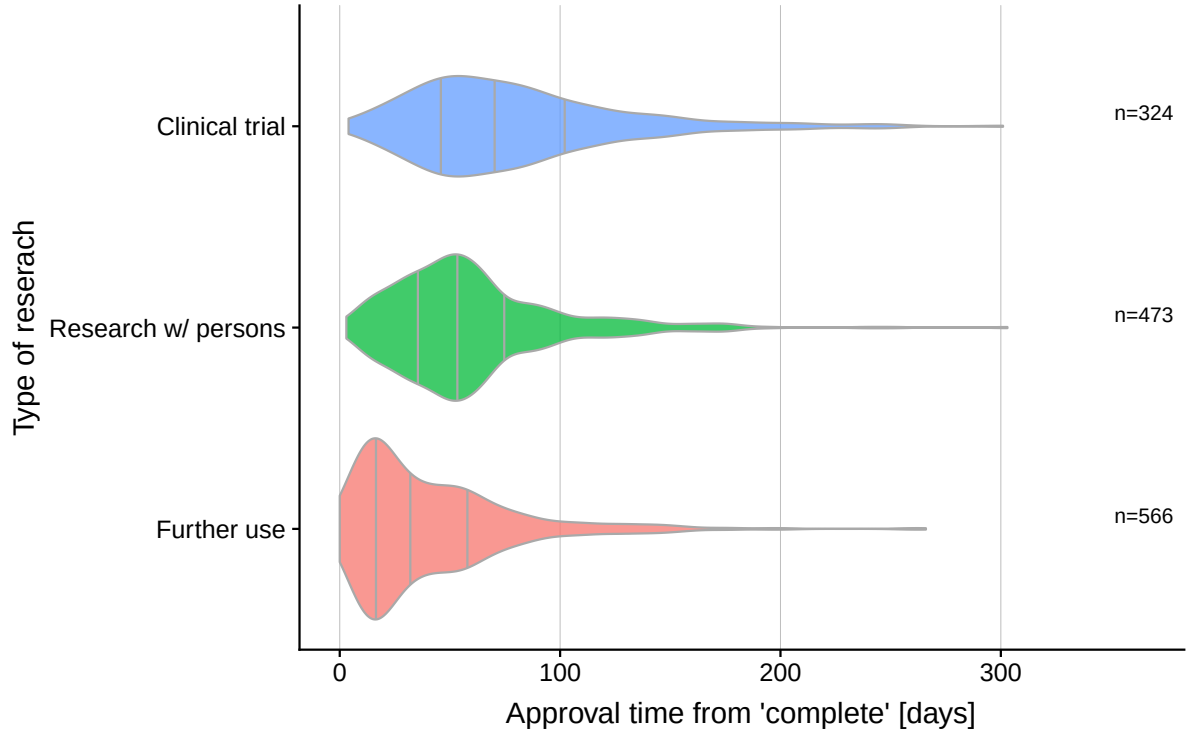


**Figure 18:** Violin plot of the **approval time starting from status ‘complete’** per type of research (only the 3 major groups are shown). 0 projects with approval time > 1 year are not shown for layout reasons.

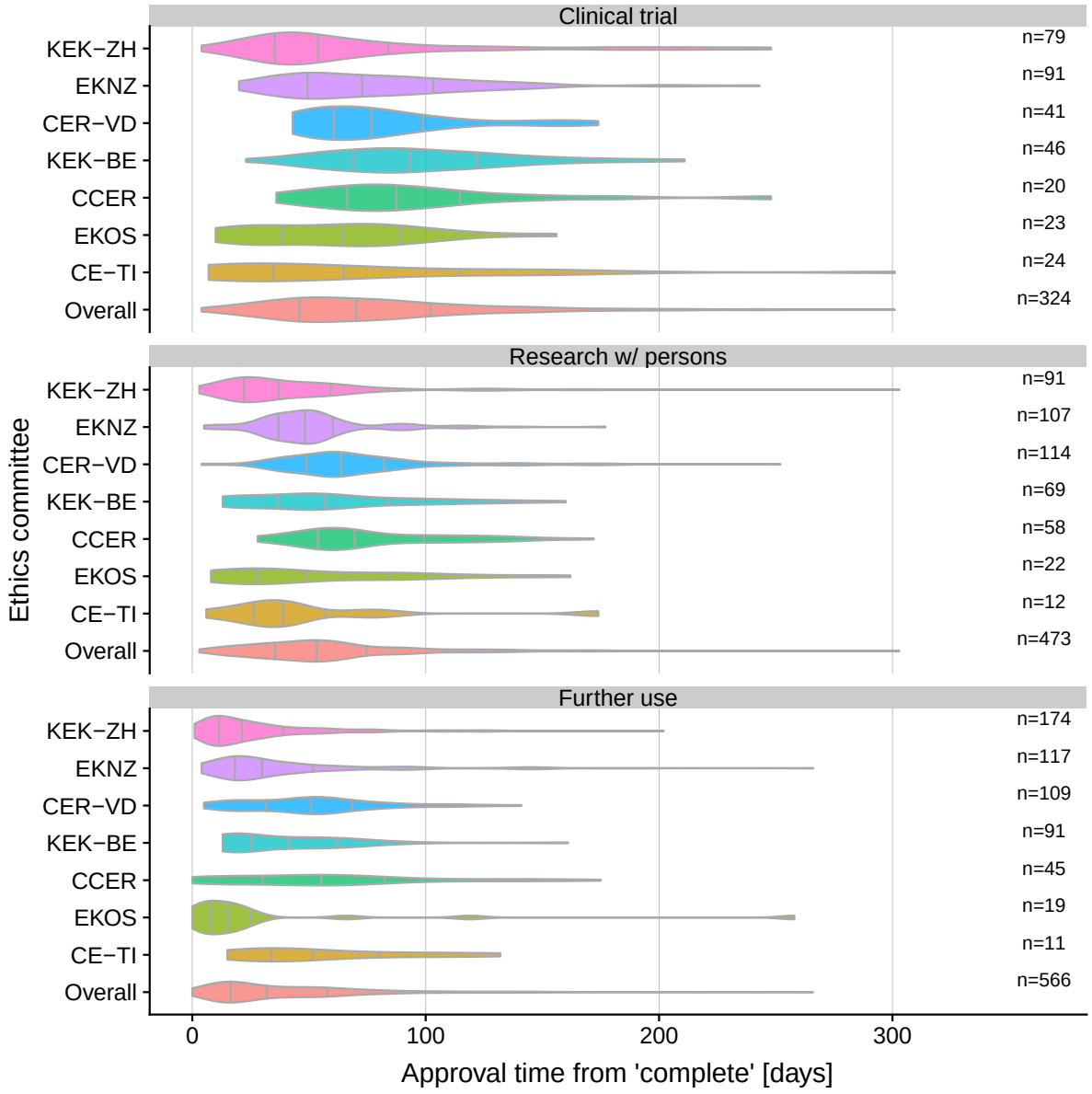


**Figure 19:** Violin plot of the **approval time starting from status 'complete'** per type of research (only the 3 major groups are shown) stratified by EC. 0 projects with approval time > 1 year are not shown for layout reasons.

### 5.4.2 Time from reception to final decision

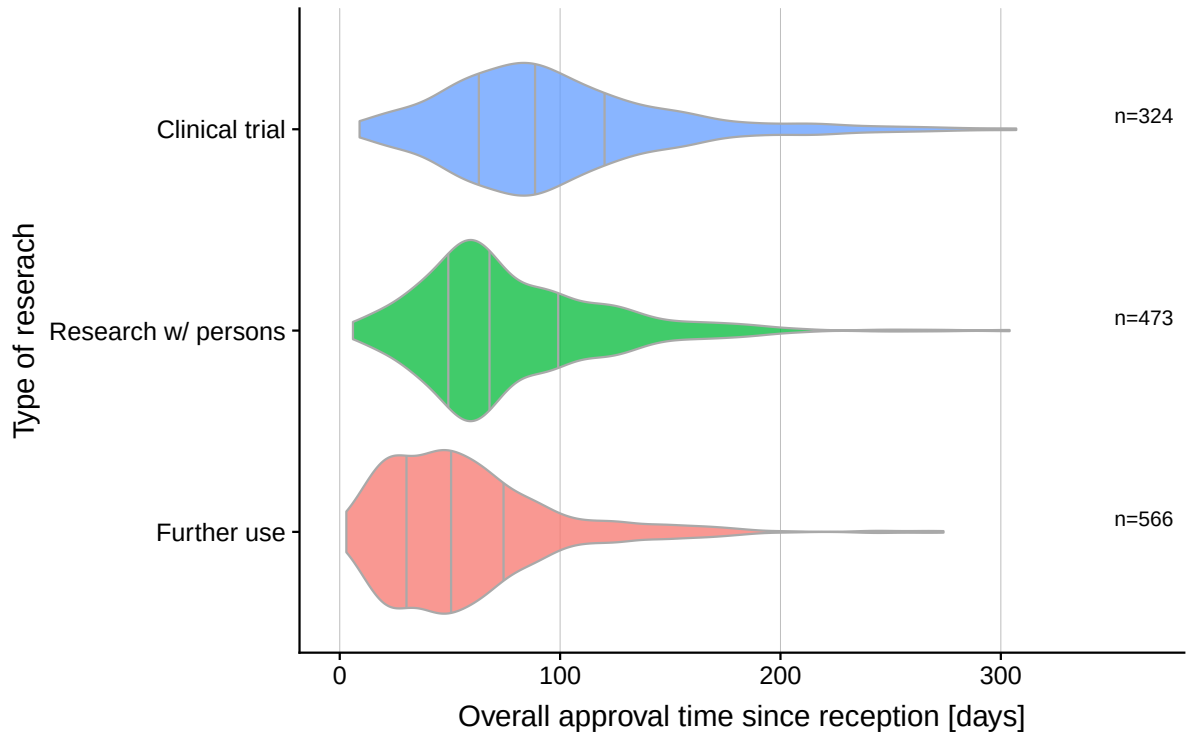


**Figure 20:** Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown). 0 projects with an overall approval time > 1 year are not shown for layout reasons.

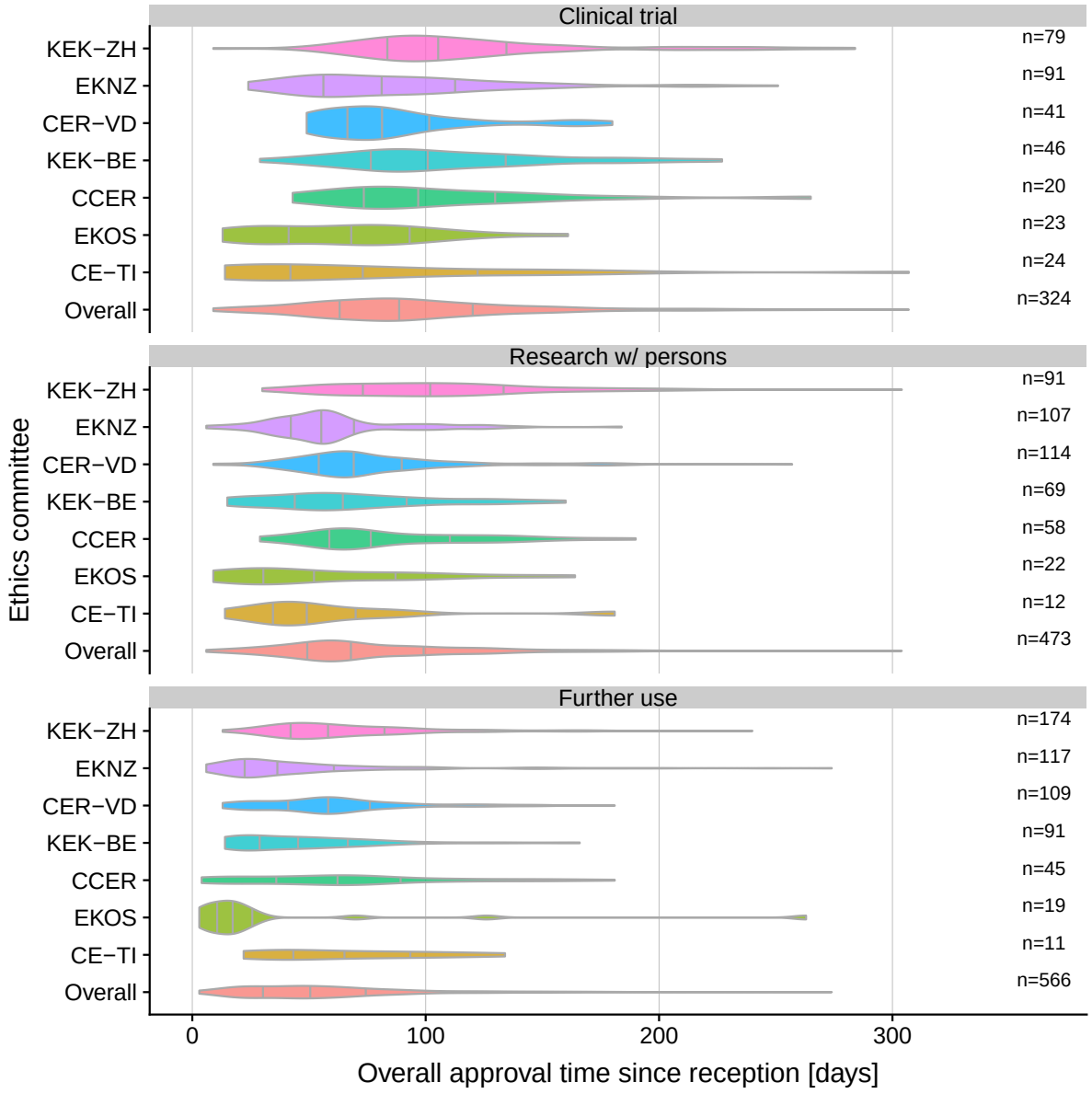


**Figure 21:** Violin plot of the **overall approval time since reception** per type of research (only the 3 major groups are shown) stratified by EC. 0 projects with an overall approval time > 1 year are not shown for layout reasons.

## 5.5 Stratification of response time by involvement of single or multiple ECs

**Description of distinctive features of the results:**

As expected, approval times for applications involving multiple ECs tend to be longer compared to applications involving a single EC. The additional time is spent between first and final decision.

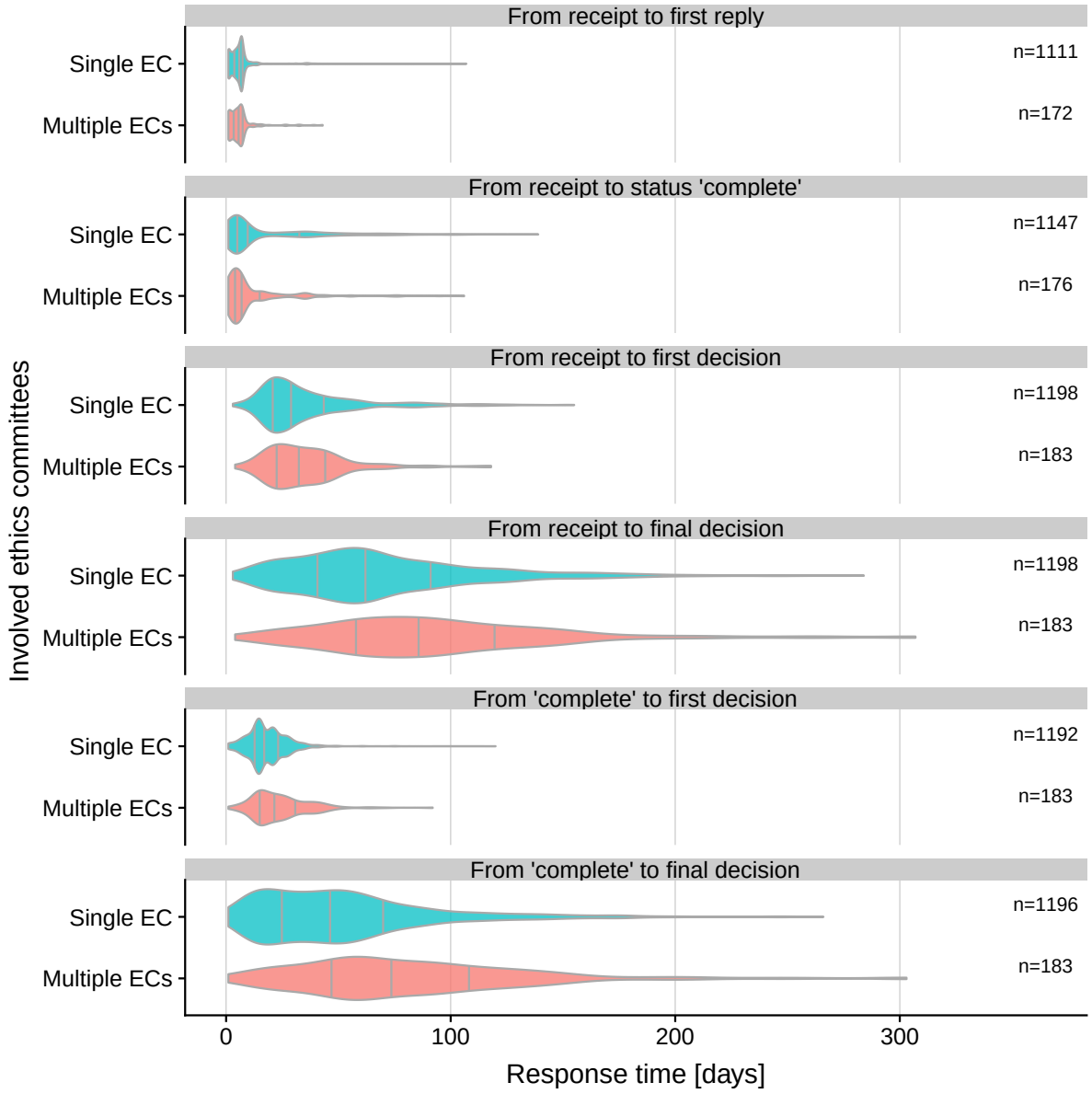


**Figure 22:** Violin plot of all response times depending on whether a single or multiple ECs were involved.

**Table 41:** Overview of response time in days - Median and inter-quartile range (IQR) per type of research (3 major groups only) and depending on whether a single or multiple ECs are involved.

| | | Application involves | | | | | |
|---|---|---|---|---|---|---|---|
| | | Multiple ECs | | | Single EC | | |
| Type of research | Time interval | n | Median | IQR | n | Median | IQR |
| Clinical trial | from receipt to first reply | 93 | 5 | [ 2, 7] | 231 | 6 | [ 4, 7] |
| | from receipt to status 'complete' | 93 | 6 | [ 3, 13] | 231 | 7 | [ 4, 30] |
| | from receipt to first decision | 93 | 37 | [ 26, 47] | 231 | 34 | [ 22, 50] |
| | from receipt to final decision | 93 | 98 | [ 79, 133] | 231 | 82 | [ 59, 113] |
| | from 'complete' to first decision | 93 | 23 | [ 16, 36] | 231 | 20 | [ 14, 28] |
| | from 'complete' to final decision | 93 | 91 | [ 63, 121] | 231 | 63 | [ 42, 90] |
| Research w/ persons | from receipt to first reply | 53 | 5 | [ 2, 7] | 420 | 5 | [ 2, 7] |
| | from receipt to status 'complete' | 53 | 5 | [ 2, 8] | 420 | 6 | [ 3, 19] |
| | from receipt to first decision | 53 | 27 | [ 20, 35] | 420 | 28 | [ 22, 44] |
| | from receipt to final decision | 53 | 69 | [ 53, 104] | 420 | 66 | [ 51, 98] |
| | from 'complete' to first decision | 53 | 19 | [ 15, 26] | 420 | 19 | [ 14, 24] |
| | from 'complete' to final decision | 53 | 59 | [ 44, 91] | 420 | 52 | [ 34, 70] |
| Further use | from receipt to first reply | 36 | 5 | [ 2, 7] | 530 | 6 | [ 2, 7] |
| | from receipt to status 'complete' | 36 | 6 | [ 3, 10] | 530 | 7 | [ 3, 27] |
| | from receipt to first decision | 36 | 30 | [ 21, 40] | 530 | 27 | [ 20, 41] |
| | from receipt to final decision | 36 | 65 | [ 44, 84] | 530 | 49 | [ 28, 72] |
| | from 'complete' to first decision | 36 | 20 | [ 14, 28] | 530 | 15 | [ 10, 21] |
| | from 'complete' to final decision | 36 | 51 | [ 26, 67] | 530 | 28 | [ 15, 56] |
| Overall | from receipt to first reply | 182 | 5 | [ 2, 7] | 1181 | 6 | [ 3, 7] |
| | from receipt to status 'complete' | 182 | 6 | [ 3, 12] | 1181 | 7 | [ 3, 26] |
| | from receipt to first decision | 182 | 32 | [ 22, 44] | 1181 | 28 | [ 21, 43] |
| | from receipt to final decision | 182 | 86 | [ 58, 119] | 1181 | 62 | [ 41, 90] |
| | from 'complete' to first decision | 182 | 22 | [ 15, 30] | 1181 | 16 | [ 13, 23] |
| | from 'complete' to final decision | 182 | 70 | [ 50, 106] | 1181 | 47 | [ 23, 69] |